UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re CHEMBIO DIAGNOSTICS, INC. SECURITIES LITIGATION	:	Civil Action No. 2:20-cv-02706-ARR-ARL **(Consolidated)**
This Document Relates To: ALL ACTIONS.	:	CONSOLIDATED AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS
	:	CONSOLIDATED CLASS ACTION

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Lead Plaintiffs Municipal Employees' Retirement System of Michigan ("MERS"), Special Situations Fund III QP, L.P. ("Fund III"), Special Situations Cayman Fund, L.P. ("Cayman Fund"), and Special Situations Private Equity Fund, L.P. ("PE Fund," and collectively with Fund III and Cayman Fund, the "Funds," and collectively with MERS, "Lead Plaintiffs"), by and through their undersigned attorneys, on behalf of themselves and all others similarly situated, allege the following based upon the investigation by Co-Lead Counsel, except as to allegations specifically pertaining to Lead Plaintiffs, which are based on personal knowledge. The investigation by Co-Lead Counsel included, among other things, a review of Chembio Diagnostics, Inc.'s ("Chembio" or the "Company") public filings with the United States Securities and Exchange Commission ("SEC"), press releases issued by the Company, public conference calls, media and news reports about the Company, and publicly available trading data relating to the price and volume of Chembio common stock.

NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of two proposed classes (the "Classes"):

(a) All persons who purchased Chembio common stock directly in or traceable to the Company's May 7, 2020 offering (the "May Offering") pursuant to Chembio's Form S-3 Registration Statement and its Prospectus and Prospectus Supplement, dated May 7, 2020 (together, the "Registration Statement"). This class asserts claims only for violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (the "Securities Act"), 15 U.S.C. §§ 77k, 77l and 77o (the "Securities Act Class"); and

(b) All persons who purchased or otherwise acquired Chembio securities on the open market between March 12, 2020 and June 16, 2020, inclusive (the "Class Period"). This class of investors asserts claims only for violations of Section 10(b) of the Securities Exchange Act of

1934 (the "Exchange Act"), 15 U.S.C. § 78j(b) and 78t(a), and Rule l0b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.1 b-5, as well as Section 20(a) of the Exchange Act (the "Exchange Act Class").

2. The ongoing COVID-19 pandemic has caused massive social and economic disruption. It has led to the largest global recession since the Great Depression, widespread supply shortages, the postponement and cancellation of events, including businesses and schools, agricultural and food shortages, and massive strains on healthcare systems, grinding global society to a halt for most of the year 2020. Early in the pandemic, diagnostic testing was identified as a lifeline necessary to restart society in the face of a growing death toll, which has now surpassed 2.28 million. The World Health Organization stated: "You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don't know who is infected. We have a simple message for all countries: test, test, test."[1] Even today, a year into the pandemic, accurate, reliable, and widely-available testing remains one of the most paramount concerns in global health.

3. This case concerns a publicly-traded diagnostic testing company that callously put profits above public health to capitalize on the public's desperate need for reliable COVID-19 testing at the outset of the pandemic.

4. Chembio's business centers on developing diagnostic solutions and products for treatment, detection, and diagnosis of infectious diseases. The Company claims to have developed and patented a new and innovative technology called the Dual Path Platform® ("DPP"), which allows for rapid diagnostic testing of a variety of infectious diseases and chemical substances. On its website, the Company maintains that its products "meet the highest standards for accuracy and

[1] *WHO Director-General's opening remarks at the media briefing on COVID-19*, WORLD HEALTH ORGANIZATION (Mar. 16, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---16-march-2020.

superior performance to help prevent the spread of infectious diseases" and that its "innovative solutions, like the Chembio Dual Path Platform (DPP®), make [point-of-care] testing faster, more accurate, and more cost effective."

5. In early 2020, diagnostic testing manufacturers and suppliers such as Chembio were perfectly positioned to capitalize on the massive demand for accurate COVID-19 tests. As COVID-19 cases continued to surge, widespread panic increased, and standards for U.S. Food and Drug Administration ("FDA") approval relaxed with the availability of Emergency Use Authorizations ("EUAs"), Chembio was highly incentivized to seize the opportunity to cash-in at the expense of its investors, without regard for testing accuracy.

6. On March 12, 2020, Chembio announced its intention to create a COVID-19 antibody test using its preexisting DPP technology, and that it had entered into a worldwide strategic partnership with LumiraDx Limited ("LumiraDx"), a company focused on developing, manufacturing, and commercializing industry-leading point-of-care diagnostic platforms, with the aim of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies on both of their DPP® platforms, later called the DPP COVID-19 IgM/IgG System (the "DPP COVID-19 Test," or the "Test").

7. At the time, the Chembio Defendants (defined below) emphasized their ability to create a COVID-19 antibody test that would be both accurate and viable for the long-term. They falsely emphasized the "scientific expertise and the versatility of our DPP platform" and stated that they "did not knee-jerk" and "don't want to be another company out there that's just making noise." The Chembio Defendants aimed to convince investors of their ability to "bring something that's commercially viable," and "that has some aftermarket impact[.]" After this announcement, Chembio's shares jumped 65% during pre-market trading.

8. Soon after, on March 20, 2020, additional statements by the Chembio Defendants, including that the DPP platform had already "enabled" Chembio "to develop a high quality test for SARS-CoV-2 efficiently and rapidly[,]" gave investors the false impression that the DPP COVID-19 Test was already an effective and commercially viable product. This further boosted the price of Chembio shares, which rose 54% on the same day. Additionally, although the DPP COVID-19 Test had not yet received an EUA from the FDA, Chembio customers, such as the Brazilian company Bio-Manguinhos, placed advance purchase orders for Chembio's DPP COVID-19 Test worth millions of dollars.

9. However, instead of ensuring that its DPP COVID-19 Test was accurate and would not put patients at unreasonable risk, the Chembio Defendants rushed the test to market without first competently verifying its accuracy, despite representing otherwise to the market and investors. This allowed Chembio to sustain its operations and gain a competitive advantage over more sophisticated competitors. Before the FDA caught on, and later revealed the truth to an unwitting public, Chembio benefited from a highly inflated share price caused by the Chembio Defendants' misrepresentations and omissions of material facts concerning the Test's true performance and commercial viability.

10. On April 14, 2020, the FDA granted an EUA to the DPP COVID-19 Test, making it one of the first such tests to gain an EUA in an extremely competitive market. This allowed Chembio to rush the Test to the market and thereby capitalize on the premium that investors were paying at that time for companies – like Chembio – that were successfully monetizing COVID testing.

11. Throughout the Class Period, the Chembio Defendants touted the Company's progress in developing the DPP COVID-19 Test, representing that it successfully aided in determining current or past exposure to COVID-19, that it provided high sensitivity and specificity

(measures of the test's accuracy), and that it was ***100% accurate*** for total antibodies after 11 days following the onset of symptoms, which helped Chembio further distinguish itself from its competitors.

12. Unsurprisingly, investors reacted very positively to these representations and the concomitant business-changing effect that a viable and highly accurate COVID-19 diagnostic test would have for the Company.

13. These misrepresentations ultimately drove the Company's stock from a closing price of $3.10 per share on March 11, 2020 to a Class Period high of $15.54 per share on April 24, 2020, an increase of ***more than 400%.***

14. To further take advantage of the Company's inflated stock price, Defendants conducted the May Offering.

15. In the May Offering, Defendants sold approximately 2.6 million shares of Chembio stock at $11.75 per share directly to the public, including the Funds, for gross proceeds of approximately $30.8 million on May 11, 2020.

16. The Registration Statement for the May Offering stated that Chembio's Test was "100% accurate" and made numerous unequivocal representations about the commercial viability of the Test and the critical FDA EUA authorization that allowed the Company to sell the Test in the United States. The Registration Statement also warned of the risk to the Company should the FDA revoke EUA, without ever disclosing that the EUA was – or was at an increased risk of – being revoked.

17. Prior to the May Offering, the Chembio Defendants had been notified by the FDA by April 29, 2020 that new information from three evaluations performed since the initial EUA grant on April 14, 2020 demonstrated that Chembio's test performance may be "both inconsistent and lower

than that described . . . ." Specifically, the data generated from an independent evaluation of Chembio's device by the Department of Health and Human Services, National Institutes of Health, and the National Cancer Institute ("NCI") demonstrated that relevant measures of the Test's accuracy fell below the percentages deemed acceptable by the FDA. Chembio was notified at the time of its original submission that the NCI would be conducting an independent evaluation, so it knew at that time – well before the May Offering – that independent government agencies would be evaluating the Company's self-serving test results.

18. Notably, Chembio had submitted additional data to the FDA on April 29, 2020 and May 15, 2020 (a time frame encompassing the May Offering), which the FDA stated did not resolve its concerns regarding the poor clinical performance of Chembio's DPP COVID-19 Test. The FDA also stated that data provided by Chembio on April 29, 2020 further demonstrated poor performance.

19. The Registration Statement did not disclose the results of this independent investigation, which had been reported to the Company well before the May Offering, and indeed omitted any reference to the results of the independent testing, which at the very least called into question the accuracy of the DPP Test and its domestic commercial viability.

20. The FDA also emailed Chembio on May 22, 2020, expressing its concern that the independent evaluation data suggested that the DPP COVID-19 Test's poor performance may put patients at unreasonable risk, and asked Chembio to submit additional information by May 25, 2020. The FDA notified Chembio that if the information it provided did not adequately address the potential risk to patients, it "may take steps and/or request that you take additional actions to protect the public health as appropriate."

21. Chembio conducted an investigation and responded to the FDA on May 24, 2020. Chembio was unable to refute the independent accuracy results, but struggled against the impending

loss of its EUA by attempting to change the methodology of the accuracy analysis, specifically by changing the cut-off for the Micro Reader II to increase the specificity of the device. The FDA strongly opposed this approach, stating that the change would be a significant modification requiring FDA approval, which it would not grant, and that even if implemented, the DPP COVID-19 Test still would not meet the EUA criteria for sensitivity and specificity.

22. Despite its obvious importance to investors, as well as the public at large who were being put in danger by Chembio's marketing of an ineffective COVID diagnostic test, the Chembio Defendants never voluntarily disclosed this information publicly, instead covering up the truth about the Test. Unfortunately for Chembio, the FDA had no choice but to notify the public, with devastating effects on Chembio's stock price and public investors.

23. On June 16, 2020, after the market closed, the FDA issued a press release disclosing that it had revoked the Company's EUA for the DPP COVID-19 Test (the "Revocation"). In a public announcement, the FDA stated that its decision was "due to performance concerns with the accuracy of the test." More specifically, the FDA informed that the Company's DPP COVID-19 Test "generate[d] a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device." As a result, the FDA concluded that the "test's benefits no longer outweigh its risks." The FDA also sent a letter addressed to Chembio dated June 16, 2020 (the "FDA Letter"), notifying the Company of the Revocation and elaborating on how the FDA reached its decision.

24. The next day, on June 17, 2020, Chembio publicly acknowledged its receipt of the FDA Letter and informed the public of the FDA's revocation of its EUA. Immediately following this disclosure, at least five analysts downgraded Chembio stock.

25. As a result of disclosure of the FDA Letter and the revocation of the EUA, Chembio shares declined from a closing price on June 16, 2020 of $9.93 per share to close at $3.89 per share on June 17, 2020, a decline of $6.04 per share, or over 60%, on unusually heavy trading volume of over 25 million shares traded.

26. Analysts that followed Chembio's stock expressed "shock" and "surprise" at the news, saying – according to Canaccord Genuity Capital Markets, for instance – that the disclosure highlighted the "execution and transparency" risk for the Company.

27. The Revocation had devastating implications for Chembio's new business model, which shifted the Company away from its prior products, which were now described as "legacy products" in the Registration Statement. The Company addressed this in its Form 10-Q, released on August 7, 2020, stating: "The diminished focus on our existing product portfolio and extensive economic disruption caused by the COVID-19 pandemic, exacerbated by the Revocation in June 2020 and the related impact on product returns and variable consideration, was reflected in our results for the six months ended June 30, 2020 as compared to the prior year period, as total revenue decreased 35.0% to $12.0 million and product sales decreased 38.3% to $9.5 million."

28. The Company's 10-Q released on November 5, 2020 revealed that the "Revocation continued to have a significant negative impact on our product revenues by triggering the recall of unused DPP COVID-19 IgM/IgG Systems from customers in the U.S. during the second quarter of 2020, precluding the sale of the systems within the U.S. during the third quarter of 2020, and also deferring certain customer opportunities for the DPP SARS-CoV-2 Systems outside the U.S." Chembio's gross product margin during the nine months ended September 30, 2020 decreased by $4.9 million, or 92%, from the comparable period of 2019.

29. As a result of Defendants' conduct, Lead Plaintiffs and other members of the Classes have suffered significant losses and damages. Lead Plaintiffs bring this lawsuit to remedy the harm caused by Defendants' materially false and misleading statements and omissions of material fact.

JURISDICTION AND VENUE

30. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2), and 15 of the Securities Act, 15 U.S.C. §§77k, 771(a)(2) and 77o and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

31. This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act and 28 U.S.C. §1331, Section 27 of the Exchange Act.

32. Venue is proper in this Judicial District pursuant to Section 22 of the Securities Act, Section 27 of the Exchange Act, and 28 U.S.C. §1391(b). Chembio is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of the acts and conduct complained of herein took place within this Judicial District.

33. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

A. Lead Plaintiffs

34. Lead Plaintiff MERS purchased Chembio common stock during the Class Period and was injured thereby, as set forth in its certification previously filed with the Court and incorporated herein by reference.

35. Lead Plaintiffs the Funds purchased Chembio common stock during the Class Period and pursuant to the Registration Statement and have been damaged thereby, as set forth in their

certification previously filed with the Court and incorporated herein by reference. The Funds collectively purchased 125,000 shares in the May Offering pursuant to the Registration Statement at the offering price of $11.75 per share.

B. The Chembio Defendants

36. Defendant Chembio is a Nevada corporation with its principal executive offices located at 555 Wireless Blvd., Hauppauge, NY 11788. Chembio's common stock trades in an efficient market on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "CEMI." Together with its subsidiaries, Chembio develops, manufactures, and commercializes point-of-care ("POC") diagnostic tests that are used to detect or diagnose diseases. Historically, Chembio's primary business has been the design and sale of rapid diagnostic tests for, among other infectious diseases, HIV, HIV-Syphilis, Syphilis, Zika, Leishmaniasis, Chagas, and Ebola to customers such as hospitals, governmental and public health entities, non-governmental organizations, medical professionals, and retail establishments primarily located in the United States, Brazil, Europe, Malaysia and Mexico. Chembio Diagnostic Systems Inc., incorporated in Delaware, is the operating subsidiary of Chembio Diagnostics, Inc. Together, the companies conduct Chembio's primary business of developing, manufacturing, marketing, and licensing POC diagnostic tests.

37. Defendant Richard L. Eberly ("Eberly") has served as Chembio's Chief Executive Officer ("CEO") and President since March 16, 2020. He was previously a Managing Director at Solid Rock Principled Capital LLC, a private equity firm focused on biomedical companies, as well as an executive at other biomedical companies.

38. On March 16, 2020, in accordance with the terms of his employment agreement, Chembio granted Eberly a restricted stock unit ("RSU") award to acquire, without payment of any purchase price, up to 233,589 shares of common stock. Eberly signed Company documents filed

with the SEC, including Chembio's Form 10-Q for the quarterly period ended March 31, 2020, filed with the SEC on May 4, 2020.

39. Defendant Gail S. Page ("Page") has served as Chembio's Executive Chair of the Board since April 23, 2020 and as a Director since 2017. Page served as Chembio's Interim CEO from January 2020 through March 15, 2020, and provided transitional services from March 16, 2020 through April 22, 2020. Page signed Company documents filed with the SEC, including the Registration Statement.

40. Defendant Neil A. Goldman ("Goldman") has served as Chembio's Executive Vice President and Chief Financial Officer ("CFO") since December 2017. Goldman signed Company documents filed with the SEC, including Chembio's Form 10-Q for the quarterly period ended March 31, 2020, filed with the SEC on May 4, 2020 and the Registration Statement.

41. Defendant Javan Esfandiari ("Esfandiari"), has served as Chembio's Executive Vice President and Chief Science & Technology Officer at all relevant times.

42. Defendants Eberly, Page, Goldman and Esfandiari are referred to herein as the "Officer Defendants;" Chembio and the Officer Defendants are collectively referred to herein as the "Chembio Defendants."

43. The Officer Defendants possessed the power and authority to control the contents of Chembio's SEC filings, press releases, and other market communications. The Officer Defendants were provided with copies of Chembio's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Chembio, and their access to material information available to them but not to the public, the Officer Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public,

and that the positive representations being made were then materially false and misleading. The Officer Defendants are liable for the false statements and omissions pleaded herein.

44. Defendant Katherine L. Davis ("Davis"), a director of Chembio, signed the Registration Statement.

45. Defendant Mary Lake Polan ("Polan"), a director of Chembio, signed the Registration Statement.

46. Defendant John Potthoff ("Potthoff"), a director of Chembio, signed the Registration Statement.

47. Defendants Davis, Polan and Potthoff are collectively referred to herein as the "Director Defendants."

C. Underwriter Defendants

48. Defendant Robert W. Baird & Co. Inc. ("Baird") is a diversified financial services firm that, among other things, offers investment banking services to public issuers of securities. Its headquarters are located at 777 East Wisconsin Avenue, Milwaukee, WI, 53202.

49. Defendant Dougherty & Company LLC ("Dougherty") is a diversified financial services firm that, among other things, offers investment banking services to public issuers of securities. Its headquarters are located at 90 South Seventh Street, Suite 4300, Minneapolis, MN, 55402.

50. Defendants Baird and Dougherty are referred to herein as the "Underwriter Defendants." The Underwriter Defendants acted as underwriters of, and as sellers in, the May Offering. As shown in the chart below, from the Prospectus Supplement, the Underwriter Defendants received the following shares:

Underwriters	Number of Shares
Robert W. Baird & Co. Incorporated	1,987,698
Dougherty & Company LLC	350,770
Total	2,338,468

51. The Underwriter Defendants were also granted the option to buy up to an additional 350,770 shares of common stock, with 30 days from the date of the prospectus to exercise this option. If any shares were purchased pursuant to this option, the underwriters agreed to severally purchase shares in approximately the same proportion as set forth in the table above. If any additional shares of common stock were purchased, the underwriters agreed to offer the additional shares on the same terms as those on which the original shares were offered.

52. In connection with the May Offering, the Underwriter Defendants marketed Chembio common stock to potential investors using materially false or misleading information about the Company, and/or omitted material information required to be disclosed in the Registration Statement. The Underwriter Defendants also caused the Registration Statement to be filed with the SEC and to be declared effective in connection with the May Offering. They are liable to Lead Plaintiffs and those similarly situated under the Securities Act.

THE SECURITIES ACT CLAIMS

Substantive Allegations Under the Securities Act

53. This part of the Complaint only asserts strict liability and negligence claims based on the Securities Act and does not allege, and does not sound in, fraud.

54. As detailed below, the Registration Statement was negligently prepared and as a result contained untrue statements of material fact, omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations governing its preparation.

55. For example, the Registration Statement failed to disclose that Chembio had been made aware before the effective date of the Registration Statement that its DPP COVID-19 Test was not as effective at detecting antibodies as the Company had represented, and that Chembio was at risk of having the Test's EUA authorization revoked by the FDA. In fact, as explained herein, the Registration Statement falsely and misleadingly represented contrary facts.

56. Any information concerning the DPP COVID-19 Test, particularly information indicating that the Test did not work as represented to the market and public health authorities, was highly material to investors, because Chembio's business model had shifted at the onset of the pandemic exclusively to COVID-19 testing and the entire thrust of the Company's business was now developing and marketing the DPP COVID-19 Test. Thus, any risk that the Company could not market the DPP COVID-19 Test domestically could be devastating to the Company's business and future prospects.

A. The Accuracy of Chembio's DPP COVID-19 Test

57. Chembio was granted an EUA for its DPP COVID-19 Test on April 14, 2020 based on clinical performance estimates of 77.4% positive percent agreement (PPA)/sensitivity for IgM, 87.1% PPA for IgG, 93.5% PPA for combined IgM/IgG, and 94.4% negative percent agreement (NPA)/specificity for combined IgM/IgG. The EUA allowed Chembio to immediately market and sell the DPP Test in the United States as a diagnostic test to evaluate the presence of COVID-19 antibodies.

58. As described by analysts at Craig-Hallum who followed Chembio stock:

> [Chembio's] DPP COVID-19 [Test] is a rapid serological point-of-care test for the detection of IgM and IgG antibodies. We would liken IgM antibodies to first responders, as [the] body generates these first at the sign of infection; in time, the IgM antibodies fade and IgG antibodies take over. Thus the DPP [T]est can help distinguish acute/active infection via IgM (and thus whether that person can transmit the virus) and prior infection via IgG (not likely to transmit the virus). . . . [R]esults are obtained within 15 minutes using a simple finger stick of blood. . . . [T]he

> Chembio DPP [COVID-19 T]est is able to provide a quantitative result, which could assist clinicians in determining patients who have been exposed to Coronavirus, irrespective of whether they are asymptomatic.

59. Test accuracy is the principal concern for serology tests like Chembio's DPP COVID-19 Test. FDA EUA is a seal of approval for such tests, and analysts covering Chembio's stock at that time concluded that FDA EUA is the "line in sand" separating reliable and accurate serology tests from the numerous dysfunctional or low-performing tests expected to enter the market at the outset of the pandemic. As a general matter, patients and their healthcare providers are more likely to seek out diagnostic tests that have met with FDA approval than alternative tests that have not been found to be as reliable.

60. At the time it received an EUA from the FDA, Chembio was the only publicly traded company with such authorization.

61. In response to Chembio's announcement that it had received an EUA from the FDA, Chembio's stock price increased rapidly, and analysts covering Chembio's stock increased their price targets for the Company, noting that, according to Canaccord Genuity on April 15, 2020, for example, the EUA "further 'legitimizes' CEMI's COVID-19 revenue opportunity and the [121% year to date] return for its stock."

62. However, the FDA privately informed Chembio by April 29, 2020 that independent evaluation data of Chembio's DPP COVID-19 Test indicated that Chembio's prior data was inaccurate and that the DPP COVID-19 Test was ineffective.

63. On April 29, 2020, the FDA told Chembio that data generated from an independent evaluation of Chembio's device by the Department of Health and Human Services, National Institutes of Health, and the NCI demonstrated an observed PPA of 57.1% for IgM, 78.6% for IgG, and 82.1% for combined IgM/IgG, which indicates a high false negative rate. The overall NPA was

81.2%, which indicates a high false positive rate. The FDA stated that these results were "both inconsistent and lower than that described in [Chembio's] original submission."

64. The performance demonstrated in the independent evaluation was below the clinical performance that the FDA generally expects for serology tests to meet the effectiveness and risk/benefit standards for issuance of an EUA. In the FDA Letter, the FDA stated that clinical agreement data for SARS-CoV-2 antibody tests with 30 positive samples and 75 negative samples generally should demonstrate a minimum combined PPA/sensitivity, of 90%; a minimum NPA/specificity, of 95%; and for tests that report specifically IgM and IgG, a minimum PPA/sensitivity for IgG of 90% and a minimum PPA/sensitivity for IgM of 70%. Clinical agreement data for SARS-CoV-2 antibody tests with greater than 30 positives and 75 negative samples generally should demonstrate a minimum overall (*i.e.*, IgM/IgG combined) and IgG PPA of 87% with a lower bound of the 95% confidence interval greater than 74.4%, a minimum IgM PPA of 67% with a lower bound of the 95% confidence interval greater than 52.1%, and a minimum NPA of 93% with a lower bound of the 95% confidence interval greater than 87.8%.

65. As a result, the data Chembio included in its EUA submission was insufficient to maintain EUA approval from the FDA and fell far below the FDA's standards for granting and maintaining EUAs. At the time of the May Offering, the DPP COVID-19 Test was considered inaccurate and ineffective by the FDA, the FDA had notified Chembio of these concerns, and Chembio had already submitted additional data to the FDA in an effort to resolve them that was insufficient.

B. The Registration Statement Failed to Disclose the True Accuracy and Prospects of Chembio's DPP COVID-19 Test

66. On October 3, 2018, Chembio filed the Registration Statement with the SEC.

67. On May 8, 2020, the Prospectus for the May Offering, which forms part of the Registration Statement, became effective. Thereafter, Defendants, including the Underwriter Defendants, offered and sold approximately 2,619,593 shares of Chembio common stock, which included 281,125 shares issued pursuant to the partial exercise by the underwriters of their option to purchase additional shares, at a public offering price of $11.75 per share for gross proceeds of approximately $30.8 million.

68. Specifically, the Registration Statement stated:

> In February 2020, we began to shift substantially all of our resources to leverage our DPP lateral flow technology to address the acute and escalating need for an accurate diagnostic test for COVID-19. By March 2020 we had developed, and begun to manufacture for commercialization, the DPP COVID-19 System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. The DPP COVID-19 System can provide discrete, numerical readings for IgM and IgG antibody levels in approximately 15 minutes from a fingerstick drop of blood. ***The accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies.***

69. The statement referenced above in ¶68 was an untrue statement of material fact because at the time of the Registration Statement, the accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms was not 100% for total antibodies.

70. The Registration Statement also discussed the Company's focus on the "manufacture and commercialization of the DPP COVID-19 System," stating:

> Prior to shifting our focus to COVID-19 testing in February 2020, we had established our company as a leading provider of diagnostic tests for infectious diseases with a broad portfolio of infectious disease products. ***We refer to our infectious disease products, other than the DPP COVID-19 System, as our legacy products. We expect to generate an immaterial amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the manufacture and commercialization of the DPP COVID-19 System.*** Thereafter, however, we intend to recommence the development, marketing, manufacture and sale of the legacy product portfolio consistent with market demand.

71. The statements referenced above in ¶70 were untrue statements of material fact and omitted to state other facts necessary to make the statements not misleading because they failed to

disclose that, at the time of the Registration Statement, the continued approval of the DPP COVID-19 System's EUA was in question, making the continued manufacture and commercialization of the DPP COVID-19 System highly uncertain.

72. The Registration Statement also failed to disclose that, at the time of the May Offering, management knew that the FDA had expressed concerns about the reliability of the data it submitted with its EUA application and that there was an increased risk that its EUA for the DPP COVID-19 System would be revoked.

73. For example, Chembio addressed other risks associated with FDA review and the EUA grant, namely:

> Our DPP COVID-19 System is subject to regulations of the U.S. Food and Drug Administration, or FDA, International Organization for Standards and other regulatory requirements. The regulations regarding the manufacture and sale of our DPP COVID-19 System ***may be unclear and are subject to change. Newly promulgated regulations could require changes to our DPP COVID-19 System, necessitate additional procedures, or make it impractical or impossible for us to market our DPP COVID-19 System for certain uses, in certain markets, or at all.*** The FDA and other regulatory authorities also have the ability to ***impose new or additional requirements*** relating to our DPP COVID-19 System. The implementation of such ***changes or new or additional requirements*** may result in substantial additional costs and could delay or make it more difficult or complicated to sell our products.
>
> The FDA issued an Emergency Use Authorization, or EUA, for emergency use of the DPP COVID-19 System. The FDA has established certain conditions that must be met to maintain authorization under an EUA, and the ***FDA also has the power to revoke the EUA under which our DPP COVID-19 System is sold if it determines that the underlying health emergency no longer exists or warrants such authorization.*** Such revocation would preclude the sale of our COVID-19 product unless and until a further regulatory approval or authorization is obtained. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.
>
> In addition, the EUA issued by the FDA for emergency use of the DPP COVID-19 System is limited to authorized laboratories certified under CLIA to perform moderate and high complexity tests. We are currently working with the FDA to approve our application for waived status under CLIA, which would permit any laboratory with a Certificate of Waiver, including physician offices and urgent care clinics, to perform the tests. ***The time required to obtain marketing authorizations***

> ***and other approvals from regulatory authorities is unpredictable.*** The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can change, and does often change, during development, which makes it difficult to predict with any certainty how they will be applied. ***We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of FDA regulatory review.***

74. The statements referenced above in ¶73 were untrue statements of material fact and omitted to state other facts necessary to make the statements made not misleading because the Registration Statement did not disclose that risks warned of had already come to pass by the date of the May Offering, namely that an independent evaluation of the DPP COVID-19 Test had revealed that the Test was far less effective than the threshold necessary to maintain EUA, and thus the Test was at risk of losing its EUA (and in fact would shortly lose it). Moreover, the Registration Statement also failed to disclose: (i) the known risk pursuant to Section 564(g)(2)(B) and (C) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3, that the FDA also had the power to revoke the EUA if the criteria in Section 564(c) was no longer met, or other circumstances made such revocation appropriate to protect the public health or safety; and (ii) that the risk and uncertainty of having the EUA revoked had increased as a result of the FDA communication before the May Offering that data underlying Chembio's EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System.

75. The Company also addressed the risks associated with the demand for its DPP COVID-19 System:

> We are committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of the DPP COVID-19 System. This resource allocation may negatively impact our legacy product portfolio, as we expect to spend limited funds and time on updating pre-existing products and regulatory approvals or on completing products that were in development prior to our strategic decision to focus on the DPP COVID-19 System. ***Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate; there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be***

> ***able to produce in quantities to meet the demand.*** We intend to reestablish our legacy business in the future, but there can be no assurance that we will be able to successfully recommence the development and commercialization of our legacy products and products under development.

76. Chembio's Form 10-Q for the quarterly period ended March 31, 2020, filed with the SEC on May 4, 2020, and incorporated by reference into the Registration Statement, stated the following:

> The market for COVID-19 diagnostic testing is new and rapidly developing, which makes it difficult to evaluate our business and future prospects. We have encountered, and will continue to encounter, risks and difficulties frequently experienced in rapidly changing industries, including those related to:
>
> - our ability to compete with companies that are currently in, or may in the future enter, the market for our products;
> - our ability to control costs, including our operating expenses;
> - our ability to successfully expand our business;
> - our ability to meet customer demand;
> - the amount and timing of operating expenses, particularly sales and manufacturing expenses, related to the maintenance and expansion of our business, operations and infrastructure; and
> - general economic and political conditions in our markets.

77. The statements referenced above in ¶¶75-76 were untrue statements of material fact and omitted to state other facts necessary to make the statements made not misleading because the Registration Statement did not disclose that the risk and uncertainty of having the EUA revoked had increased as a result of the FDA communication before the May Offering that data underlying Chembio's EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System, and as such, there was an increased risk that its business would be negatively impacted.

78. The Registration Statement also misstated the Company's ability to leverage its DPP platform to create an accurate COVID-19 serological test, and to similarly expand into other types of diseases:

> When the novel coronavirus emerged, we were confident that we could leverage our DPP platform and our scientific and operational expertise to create an antibody test to detect and diagnose the presence, or former presence, of antibodies generated in response to the virus. ***The speed with which we were able to develop a test for COVID-19 illustrates the DPP platform's applicability to new and emerging infectious diseases.***

79. The Registration Statement also stated:

> We believe our deep experience with infectious diseases, including our development of tests that can multiplex as many as eight different diseases with a single drop of blood and deliver numerical results with our Micro Readers, ***illustrates our ability to expand our DPP technology into a broader range of tests***.

80. The Registration Statement even claimed that Chembio would be able to build upon its existing EUA for the DPP COVID-19 Test:

> Under the EUA for the DPP COVID-19 System, we are permitted to sell to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform moderate and high complexity tests. We are currently focusing our sales efforts on target hospitals and state and city health departments authorized to perform moderate and high complexity tests in regions that have been most effected by the pandemic. Because we anticipate larger institutions and employers will have increasing interest in COVID-19 tests as the world evaluates its path back to work and whether individuals may have been exposed to, and may have immunity from, COVID 19, ***we are working with the FDA to identify and understand the requirements and guidelines*** that would be applicable if we were able to receive a certificate of waiver under CLIA with respect to the DPP COVID-19 System.

81. The statements referenced above in ¶¶78-79 were untrue statements of material fact and omitted to state other facts necessary to make the statements made not misleading because the Registration Statement failed to disclose that the Company's DPP COVID-19 Test did not provide high-quality results and that the data underlying Chembio's EUA application was overstated and inconsistent with than that of independent evaluations of the DPP COVID-19 System.

82. On June 16, 2020, after the market closed, the FDA issued a press release disclosing the Revocation, stating that its decision was "due to performance concerns with the accuracy of the test" that the FDA had notified the Company of before the May Offering. Following this announcement, Chembio shares declined from a closing price on June 16, 2020 of $9.93 per share to close at $3.89 per share on June 17, 2020, a decline of $6.04 per share, or over 60%.

Failure to Disclose Information Required by Items 303 and 105 of Regulation S-K

83. In addition to the materially false and misleading statements in the Registration Statement identified above, Defendants (other than Eberly and Esfandiari) also violated their affirmative obligations to provide certain material information in the Registration Statement as required by applicable SEC rules and regulations.

84. Item 303 of SEC Regulation S-K, 17 C.F.R. §229.303 ("Item 303"), requires the Registration Statement to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a materially favorable and unfavorable impact on the sales or revenues or income from continuing operations."

85. In May 1989, the SEC issued an interpretive release on Item 303 ("1989 Interpretive Release"), stating, in pertinent part, as follows:

> Required disclosure is based on currently known trends, events, and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.
>
> * * *
>
> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

86. Further, the 1989 Interpretive Release sets forth the following test to determine if disclosure under Item 303(a) is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:
>
> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
>
> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

87. By the time of the May Offering, the FDA had already communicated to Chembio that data underlying its EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System. Thus, whether the FDA would continue to allow the EUA for the DPP COVID-19 System based on the data and application submitted was a known uncertainty that was then having, and would continue to have, an unfavorable impact on the Company's revenues and income from continuing operations, and was therefore required to be disclosed in the Registration Statement but was not.

88. In addition, Item 105 of SEC Regulation S-K, 17 C.F.R. §229.105 ("Item 105"), required, in the "Risk Factors" section of the Registration Statement, a discussion of the most significant factors that made the offering risky or speculative, and that each risk factor adequately describe the risk.

89. The Registration Statement failed to disclose that there was an increased risk that Chembio's EUA for the DPP COVID-19 System could be revoked because the FDA had told Chembio that data underlying Chembio's EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System. Because this risk was not disclosed, Defendants (other than Eberly and Esfandiari) violated Item 105.

The Role of the Underwriter Defendants in Connection with the May Offering

90. The May Offering was a firm commitment offering conducted by and through the Underwriter Defendants, a syndicate consisting of Baird acting as sole book-running manager and Dougherty as co-manager.

91. The Underwriter Defendants participated in the violations complained of herein as detailed below.

92. The Underwriter Defendants are investment banking houses that, among other things, specialize in underwriting public offerings of securities. They served as the underwriters of the May Offering and shared more than one million dollars in fees collectively for doing so.

93. The Underwriter Defendants also demanded and obtained an agreement from the Chembio Defendants to indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws.

94. Representatives of the Underwriter Defendants also assisted Chembio in planning the May Offering, and had access to confidential corporate information concerning Chembio's operations and financial prospects, including information regarding the efficacy of the DPP COVID-19 Test and the FDA's response to the Company in connection therewith.

95. In addition to availing themselves of virtually unlimited access to internal corporate documents, on information and belief, agents of the Underwriter Defendants met with Chembio's lawyers, management, and top executives in the month leading up to the May Offering.

96. During these meetings, agreements were reached as to: (i) the strategy to best accomplish the May Offering; (ii) the terms of the May Offering, including the price at which Chembio common stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement.

97. As a result of those frequent contacts and communications between the Underwriter Defendants and the Chembio Defendants (as well as the Underwriter Defendants' direct involvement in material issues requiring disclosure, including Chembio's business performance and reported financial information), the Underwriter Defendants knew of, or in the exercise of reasonable care should have known of, the existing yet undisclosed conditions and material risks detailed herein, which were either misrepresented in or omitted from the Registration Statement.

98. At a minimum, the Underwriter Defendants were negligent in not knowing, and failing to disclose in connection with the May Offering, the adverse information about the DPP COVID-19 Test conveyed by the FDA to the Company before the Offering, as well as adverse information about the effectiveness of the Test that was contrary to the disclosures in the Registration Statement, the omission of which rendered the Registration Statement false and misleading at the time it was made effective.

99. The Underwriter Defendants helped cause the Registration Statement to be filed with the SEC and declared effective in connection with the offer and sale of the shares of Chembio common stock registered thereby, including those shares purchased by the Funds and other members of the Securities Act Class.

Class Action Allegations by the Securities Act Class

100. The Funds bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(3) on behalf of all persons who purchased Chembio common stock directly in or traceable to the May Offering pursuant to the Registration Statement. This class asserts claims only for violations of Sections 11, 12(a)(2), and 15 of the Securities Act, 15 U.S.C. §§77k, 77l and 77o. This class does not assert any claims sounding in fraud. Any person who did not acquire their Chembio shares directly in or traceable to the May Offering and pursuant to the Registration Statement is not included in the Securities Act Class. Also excluded from the Securities

Act Class are Defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

101. The members of the Securities Act Class are so numerous that joinder is impracticable. The May Offering involved the issuance and sale of at least 2.6 million shares of Chembio stock, which were publicly traded on the NASDAQ following the May Offering. While the exact number of Securities Act Class members is unknown to the Funds at this time, the Funds believe that there are at least thousands of members in the proposed Securities Act Class. Record owners and other members of the Securities Act Class may be identified from records maintained by Chembio or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

102. The Funds' claims are typical of the claims of the Securities Act Class, as all Securities Act Class members were and are similarly affected by Defendants' conduct.

103. The Funds will fairly and adequately protect the interests of Securities Act Class members and have retained counsel competent and experienced in securities class action litigation.

104. Common questions of law and fact exist as to all Securities Act Class members and predominate over any questions solely affecting individual Securities Act Class members. Among the common questions of law and fact are:

(a) whether Defendants violated the Securities Act;

(b) whether the Registration Statement misrepresented and/or omitted material facts in violation of the Securities Act; and

(c) whether and to what extent Securities Act Class members have sustained damages and the proper measure of damages.

105. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Securities Act Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and impracticable, for Securities Act Class members to individually redress the alleged wrongs done to them. There will be no difficulty in managing this action as a class action.

COUNT I

For Violations of §11 of the Securities Act
Against All Defendants Other than Defendants Eberly and Esfandiari

106. The Funds repeat and reallege the above allegations in ¶¶1-2, 4, 6, 15-17, 19, 23-25, 30-42, and 44-105 as if fully set forth herein.

107. This Cause of Action is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Securities Act Class, against all Defendants other than Defendants Eberly and Esfandiari. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of Section 11, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

108. Section 11 gives rise to liability to certain defendants enumerated therein if "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading. . . ." 15 U.S.C. §77k(a).

109. Among others, Section 11 identifies the following categories of defendants as those who may be liable thereunder: (a) "every person who signed the registration statement"; (b) "every person who was a director of (or person performing similar functions) . . . the issuer at the time of the filing of the part of the registration statement with respect to which his liability is asserted"; (c)

"every person who, with his consent, is named in the registration statement as being or about to become a director, person performing similar functions, or partner"; and (d) "every underwriter with respect to such security." 15 U.S.C. §77k(a)(1)-(3), (5).

110. The prospectus and prospectus supplement, which were incorporated in and formed part of the Registration Statement for the May Offering, contained inaccurate and misleading statements of material fact, omitted facts necessary to render statements therein non-misleading, and omitted to state material facts required to be stated therein.

111. Chembio is the registrant for the May Offering. Defendants named herein were responsible for the contents and dissemination of the Registration Statement, and the Director Defendants, Page and Goldman each signed and/or authorized the signing of the Registration Statement or were designated therein as director-nominees. The Underwriter Defendants marketed and underwrote the May Offering and sold Chembio common stock to investors.

112. As the issuer of the shares, Chembio is strictly liable to the Funds and the Securities Act Class for the Registration Statement's material misstatements and omissions. Signatories of the Registration Statement and the other defendants named herein are also strictly liable to the Funds and the Securities Act Class for such material misstatements and omissions.

113. None of Defendants named herein made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Registration Statement were complete, accurate or non-misleading.

114. By reason of the conduct alleged herein, each defendant violated, and/or controlled a person who violated, Section 11 of the Securities Act.

115. The Funds purchased Chembio common stock pursuant to the Registration Statement.

116. The Funds and the Securities Act Class have sustained damages. The value of Chembio common stock has declined substantially subsequent and due to Defendants' violations.

117. At the time of their purchases of Chembio common stock, the Funds and other members of the Securities Act Class were without knowledge of the facts concerning the wrongful conduct alleged herein.

118. Less than one year elapsed from the time that the Funds discovered, or reasonably could have discovered, the facts upon which this complaint is based to the time that Lead Plaintiffs filed this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time this action was filed.

COUNT II

For Violations of §12(a)(2) of the Securities Act
Against All Defendants Other than Defendants Eberly and Esfandiari

119. The Funds repeat and reallege the above allegations in ¶¶1-2, 4, 6, 15-17, 19, 23-25, 30-42, and 44-118 as if fully set forth herein.

120. This Cause of Action is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §771(a)(2), on behalf of the Securities Act Class, against all Defendants other than Defendants Eberly and Esfandiari. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of Section 12(a)(2), and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

121. Section 12(a)(2) gives rise to liability as to "[a]ny person who . . . offers or sells a security . . . by means of a prospectus or oral communication, which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading. . . ." 15 U.S.C. §771(a)(2).

Liability for a violation of Section 12(a)(2) extends to those, at a minimum, who passed title to the security to the purchaser, as well as those who solicited the purchase.

122. By means of the defective prospectus, which was incorporated in and formed part of the Registration Statement for the May Offering, these defendants promoted and sold, for the benefit of themselves and their associates, Chembio common stock to the Funds and other members of the Securities Act Class. In the absence of their efforts to publicize the May Offering and solicit Chembio common stock purchasers, the May Offering could not have occurred.

123. Additionally, Chembio qualifies as a statutory seller under SEC Rule 159A, which provides that an issuer is a statutory seller for the purpose of Section 12(a)(2) regardless of the form of underwriting. Specifically, SEC Rule 159A(a), 17 C.F.R. §230.159A(a)(1)- (4), provides, in part, the following "[d]efinition of seller for purposes of section 12(a)(2) of the [1933] Act":

> For purposes of section 12(a)(2) of the Act only, in a primary offering of securities of the issuer, regardless of the underwriting method used to sell the issuer's securities, seller shall include the issuer of the securities sold to a person as part of the initial distribution of such securities, and the issuer shall be considered to offer or sell the securities to such person, if the securities are offered or sold to such person by means of any [prospectus] . . . [or] other communication that is an offer in the offering made by the issuer to such person.

124. Furthermore, for the purpose of SEC Rule 159A(a), "information is provided or a communication is made by or on behalf of an issuer if an issuer or an agent or representative of the issuer authorizes or approves the information or communication before its provision or use." Note 1, 17 C.F.R. §230.159A(a); *see also* 70 Fed. Reg. 44722 at 44769 (Aug. 3, 2005).

125. The Registration Statement contained untrue statements of material fact and failed to disclose material facts, as detailed above. Defendants owed the Funds and other Securities Act Class members a duty to make a reasonable and diligent investigation of the statements contained in the Registration Statement to ensure they were true and accurate. Defendants, in the exercise of

reasonable care, should have known of the misstatements and omissions contained in the Registration Statement as set forth above.

126. The Funds did not know, nor in the exercise of reasonable diligence could have known, of the untruths and omissions contained in the Registration Statement when they purchased Chembio common stock.

127. By reason of the conduct alleged herein, these Defendants violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, the Funds and other members of the Securities Act Class who purchased Chembio common stock pursuant to the Registration Statement sustained substantial damages in connection with their purchases. Accordingly, the Funds and the other members of the Securities Act Class who hold Chembio common stock issued pursuant to the Registration Statement have the right to rescind and recover the consideration paid for their shares, and hereby tender their Chembio common stock to the defendants sued herein. Securities Act Class members who have sold their Chembio common stock seek damages to the extent permitted by law.

COUNT III

For Violations of §15 of the Securities Act
Against the Director Defendants, Page and Goldman

128. The Funds repeat and reallege the above allegations in ¶¶1-2, 4, 6, 15-17, 19, 23-25, 30-42, and 44-128 as if fully set forth herein.

129. This Cause of Action is brought pursuant to Section 15 of the Securities Act against the Director Defendants, Page and Goldman. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of Section 15, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

130. Where a violation of Section 11 or Section 12(a)(2) occurs, Section 15 gives rise to liability as to "[e]very person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under sections 77k or 77l [§11 or §12(a)(2)]. . . ." 15 U.S.C. §77o(a). Control persons under Section 15 are "liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable. . . ." *Id.*

131. As detailed herein, each of the Director Defendants, Page and Goldman, committed primary violations of the Securities Act, or are directly responsible and primarily liable for any such violations, by committing conduct in contravention of Sections 11 and 12(a)(2).

132. The Company controlled the Director Defendants, Page and Goldman, each of whom signed the Registration Statement.

133. The Director Defendants, Page and Goldman, each were control persons of Chembio by virtue of their positions as directors and/or senior officers of the Company. They each had direct and/or indirect business and/or personal relationships with other directors, officers and/or major shareholders of Chembio. Alternatively, the Company controlled the Director Defendants, Page and Goldman, given the influence and control the Company possessed and exerted over them.

134. By reason of the conduct alleged herein, these Defendants violated Section 15 of the Securities Act, and the Funds and the Securities Act Class have suffered harm as a result.

THE EXCHANGE ACT CLASS CLAIMS

A. Background on Chembio

135. Chembio is a provider of point-of-care ("POC") diagnostic products for the detection and diagnosis of infectious diseases. POC testing refers to medical diagnostic testing that takes place at or near the time and place of patient care. It purportedly generates real-time, lab-quality

diagnostic results within minutes through the use of portable blood analyzers, allowing medical personnel to make rapid triage and treatment decisions when diagnosing a patient or monitoring a treatment response.

136. Chembio's commercially available products employ either its proprietary DPP technology or traditional lateral flow technology. In the Registration Statement issued in connection with the May Offering, the Company claimed that in recent years, it had, while concurrently developing its own products, executed a strategy to leverage DPP intellectual property, as well as its scientific and operational expertise, through the Research and Development Services program of collaborative projects.

137. Chembio also disclosed that it is primarily focused on expanding its product portfolio based upon its proprietary DPP technology. Chembio's DPP technology is a form of lateral flow immunoassay (also referred to as lateral flow tests, referenced herein as "LFTs"), which is a diagnostic device used to confirm the presence or absence of a target analyte, such as pathogens or biomarkers in humans or animals, including antibodies or antigens. The term "assay" is the technical term for an investigative procedure for measuring the presence, amount, or functional activity of a target entity. These tests involve the application of serum or other samples directly on a strip of suitable material such as cellulose, where the antibodies are diffused laterally and eventually reach a site in the strip where appropriate antigen has been applied and chemically fixed. Specific antibodies would become bound to the site while nonreacting antibodies diffuse out from the area. The presence of antibodies is visualized using labeled conjugates. LFTs also typically contain a control line to confirm that the test is working properly, along with one or more target or test lines.

138. LFTs are designed to incorporate intuitive user protocols and are commonly advertised as requiring minimal training to operate. They can be qualitative and read visually, or

provide data when combined with reader technology, such as Chembio's DPP Micro Reader and DPP Micro Reader II, both of which were incorporated into Chembio's DPP COVID-19 System.

139. Chembio's DPP Micro Reader and DPP Micro Reader II are portable, battery-powered instruments that capture an image of the test strip surface, verify the presence and intensity of the control line, and measure the line intensity at each of the test line positions. The DPP Micro Reader interprets the test results using a scoring algorithm, and reports a "reactive," "non-reactive," or "invalid" result after approximately 3 seconds. The DPP Micro Reader II interprets the results using a test-specific algorithm, and reports a "reactive," "non-reactive," or "invalid" result after approximately 10 seconds.

140. At all relevant times, Chembio touted its proprietary DPP technology platform as easy-to-use, and providing high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. The Company claims that through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, which can deliver greater clinical value than other rapid tests. The DPP Micro Reader is described as well-suited for decentralized testing, providing real-time results to enable patients to be clinically assessed while they are still on-site. Chembio has also stated that objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

B. The Intense Demand for Accurate COVID-19 Tests in 2020 and Emergency Use Authorization

141. In late 2019, a novel virus called SARS-CoV-2, later designated as COVID-19, originated in China and spread rapidly, ultimately causing a massive global health crisis with a death toll that continues to rise, putting massive stress on the public and private health systems, and continuously exposing inefficiencies in national and global infrastructure. On February 4, 2020, the

Secretary of the Department of Health and Human Services determined, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act that there was a public health emergency with a significant potential to affect national security or the health and security of United States citizens living abroad. The COVID-19 outbreak was declared a pandemic by the World Health Organization on March 11, 2020, and the United States declared a national emergency shortly thereafter, on March 13, 2020.

142. In attempting to contain, control, and prevent the mass transmission of COVID-19, and its devastating effects, world leaders, including United States government officials and public health officials, implemented extraordinary policy measures mandating quarantining and social distancing measures. United States officials have also worked with private companies to develop COVID-19 tests, treatments, and vaccines.

143. It has become a well-known fact that accurate methods of testing for COVID-19 are a vitally important tool for reducing the spread of the virus and re-starting global society. Accurate diagnostic and serological tests that are readily accessible to the public can provide much-needed data on where the most serious outbreaks of the virus occur, and can offer insight into where medical and other resources should be allocated, and what public policy measures are appropriate or effective.

144. As a result, the demand for accurate tests has skyrocketed. The sudden worldwide demand for accurate, high-quality testing is unlike anything the diagnostic testing industry has experienced before and has placed unprecedented strain on companies attempting to tap into this new market. Test manufacturers are challenged to scale up productions, from millions of tests per month to millions per week, in the face of multiple waves of infections. The sum total of all lateral flow rapid diagnostic tests per year, approximately 2 billion globally, now conservatively needs to be

produced just for COVID-19. If every current manufacturer of these tests fully dedicated their production solely to COVID-19, there would likely still be insufficient capacity.

145. The FDA has also taken the extraordinary step of granting EUAs for hundreds of COVID-19 diagnostic and antibody tests, allowing companies to market tests without receiving formal FDA approval.

146. Before the FDA may issue an EUA, the HHS Secretary must declare that circumstances exist justifying the authorization. This is referred to as an "EUA declaration," which must be based on one of the following actions:

(a) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a CBRN agent(s);

(b) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent(s);

(c) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent(s); or

(d) the identification of a material threat, by the Secretary of Homeland Security pursuant to Section 319F-2 of the Public Health Service (PHS) Act, that is sufficient to affect national security or the health and security of United States citizens living abroad.

147. When an EUA declaration is terminated, any EUAs issued based on that declaration will no longer remain in effect. However, the FDA may decide to approve the product for the use permitted by the EUA, meaning that the product would no longer be unapproved.

148. The type of review that the FDA conducts for an EUA is considerably less rigorous than the normal process of reviewing a product for approval. Normally, to approve a drug, the FDA must determine that there is "substantial evidence," consisting of adequate and well-controlled investigations, that the product will have the effect it is intended to have. An EUA, on the other hand, can be authorized if "it is reasonable to believe that . . . the product *may* be effective." The FDA assesses the potential effectiveness of possible EUA products on a case-by-case basis using a risk-benefit analysis, which takes the material threat which prompted the EUA declaration into account.

149. The FDA has acknowledged that comprehensive effectiveness data is unlikely to be available for every EUA candidate, but recommends that an EUA request include a well-organized summary of the available scientific evidence regarding the product's safety and effectiveness, risks and benefits, and any available, approved alternatives to the product. The FDA also states that it may seek additional data and information on a case-by-case basis to ensure that their criteria are met.[2] Companies are also expected to continue to develop their product. Indeed, Chembio acknowledged that the FDA's original letter of authorization for the EUA required Chembio's participation in the NCI study, which later debunked the data included in Chembio's submission.

[2] *Emergency Use Authorization of Medical Products and Related Authorities*, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

C. Background on Serology Testing

1. The Mechanics of Serology Testing

150. There are currently two types of COVID-19 tests, diagnostic tests and serology tests, also known as antibody tests. There are two types of diagnostic tests: (1) molecular tests, such as RT-PCR tests, that detect the virus's genetic material; and (2) antigen tests that detect specific proteins from the virus. While diagnostic tests can determine if a person has an active coronavirus infection, serology tests, also known as antibody tests or immunoglobulin tests, can show if a person has been infected with COVID-19 in the past by detecting antibodies created by the immune system to fight the virus. Both are important tools in the efforts to open up the economy, return to work, and provide widespread access to vaccines.

151. Serology tests measure the level of certain antibodies, called immunoglobulins, which are proteins made by the immune system to fight antigens, such as bacteria, viruses, and toxins, in the blood. They are usually taken via finger stick or blood draw, and can provide results on the same day, or in 1-3 days. Antibodies are found in the liquid part of blood, called serum or plasma, and are specific to the particular infection they are produced to fight against.

152. The body produces different types of antibodies based on the time of infection. There are five subclasses of antibodies:

(a) Immunoglobulin A ("IgA") is found in high concentrations in the mucous membranes, particularly those lining the respiratory passages and gastrointestinal tract, as well as in saliva and tears, and may increase during infection;

(b) Immunoglobulin G ("IgG"), the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections, is commonly produced seven to fourteen days after infection, and is detectable for months and even years, depending upon the

antigen and the individual. They are more durable than IgM antibodies and could be the key to lasting COVID-19 immunity;

(c) Immunoglobulin M ("IgM"), which is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection and is commonly detectable after four to seven days. They are short-lived and may indicate that the virus is still present;

(d) Immunoglobulin E ("IgE") is associated mainly with allergic reactions and is found in the lungs, skin, and mucous membranes; and

(e) Immunoglobulin D ("IgD") exists in small amounts in the blood, and is the least-understood antibody.

153. Antibodies in some individuals can be detected within the first week of illness onset. In COVID-19 infections, IgM and IgG antibodies can arise nearly simultaneously in serum within 2 to 3 weeks after illness onset, but it is unclear how long they remain detectable following an infection. Thus, the absence of detectable IgM or IgG antibodies does not necessarily rule out that a person could have previously been infected.

154. IgA, IgG, and IgM are often measured together, to increase test specificity and give doctors more information about immune system functioning. Total IgG and IgM assays cannot distinguish between early (IgM) and late (IgG) antibody responses, and as a result, do not provide a clear picture about whether an individual has potentially developed a longer-term immune response (IgG) or is currently infected (IgM).

155. Alternatively, an IgG-specific serology test reveals if a person had COVID-19 in the past and has developed antibodies that are highly specific to the virus. While it is still uncertain whether IgG antibodies offer lasting SARS-CoV-2 immunity, the IgG-specific test is still able to tell

clinicians of a past infection, which can provide important information regarding individual and population immunity levels.

156. There are various types of serology tests that have been utilized for the detection of COVID-19 antibodies:

(a) **Rapid diagnostic test ("RDT"):** This is typically a qualitative (positive or negative) lateral flow assay that is small, portable, and can be used at the point of care. These tests may use blood samples from a finger prick, saliva samples, or nasal swab fluids. RDTs are often similar to pregnancy tests, in that they show the user colored lines to indicate positive or negative results. In the context of COVID-19, these tests most frequently test for patient antibodies (IgG and IgM), or viral antigen. The Chembio DPP COVID-19 Test is an RDT.

(b) **Enzyme-linked immunosorbent assay ("ELISA"):** This test can be qualitative or quantitative and is generally a lab-based test. They usually use whole blood, plasma, or serum samples from patients, and rely on a plate coated with a viral protein of interest. The samples are then incubated with the protein, and if the patient has antibodies to the viral protein, they bind together. The bound antibody-protein complex can then be detected with another wash of antibodies that produce a color or fluorescent-based readout. In the context of COVID-19, these tests most frequently test for patient antibodies (IgG and IgM). On its website, Chembio alleges that its DPP technology differs from classical lateral flow tests by operating in a manner similar to that of the sequential ELISA format.

(c) **Neutralization assay:** These tests rely on patient antibodies to prevent viral infection of cells in a lab setting, and require whole blood, serum, or plasma samples from the patient. They depend on cell culture, a lab-based method of culturing cells that allow SARS-CoV-2 growth. When the virus and cells are grown with decreasing concentrations of patient antibodies,

researchers can visualize and quantify how many antibodies in the patient serum are able to block virus replication, which can happen through the antibody binding to an important cell entry protein on the virus.

(d) **Chemiluminescent immunoassay:** This test is typically quantitative, lab-based, and uses whole blood, plasma, or serum samples from patients. A variation of this test can use magnetic, protein-coated microparticles, known as a chemiluminescent microparticle immunoassay. The test relies on mixing patient samples with a known viral protein, buffer reagents, and specific enzyme-labeled antibodies that allow a light-based, luminescent read-out. Any antibodies in the patient sample that react to the viral protein will form a complex. Then, secondary enzyme-labeled antibodies are added that bind to these complexes. This binding induces a chemical reaction that produces light. The amount of light, or radiance, emitted from each sample is then used to calculate the number of antibodies present in a patient sample. This test can look for multiple types of antibodies, including IgG, IgM, and IgA.

157. According to the Mayo Clinic, antibody testing is not recommended until at least 14 days after the start of symptoms. If a patient is tested too early, while their immune system is still mounting its defense, the test may not provide an accurate result. Currently, there is no identified advantage whether the assays test for IgG, IgM and IgG, or total antibody.

2. The Importance of Serology Testing for COVID-19

158. Numerous serologic assays for SARS-CoV-2 have gained EUAs in recognition of their importance in fighting the COVID-19 pandemic. Although serology tests do not detect the presence of the SARS-CoV-2 virus itself, they can help determine whether the individual being tested was previously infected, even if that person never showed symptoms, unlike direct detection methods, such as antigen detection tests, that can detect acutely infected persons. As a result, serology tests can illuminate the population's level of immunity, a key tool in society's efforts to

move past the pandemic. While serologic assays do not typically replace direct detection methods as the primary tool for diagnosing an active SARS-CoV-2 infection, they are sometimes performed along with viral testing when someone seeks care late in the course of their illness. They may also help confirm a diagnosis of Multisystem Inflammatory Syndrome in Children, a condition linked to COVID-19.

159. Serology tests have numerous important applications in monitoring and responding to the COVID-19 pandemic. Not everyone who has had COVID-19 had the opportunity to be tested before the virus was cleared from their bodies, and studies conducted on the transmission of COVID-19 to date have shown that up to 44% of those who test positive are asymptomatic. Thus, serologic assays for SARS-CoV-2 can play an important role in understanding the virus's epidemiology in the general population and identifying groups at higher risk for infection. Demographic and geographic patterns of serologic test results can also help determine which communities may have experienced a higher infection rate and therefore may have a higher proportion with some degree of immunity, at least temporarily.

160. It is now presumed that there is a significant population in the United States that likely has been infected with SARS-CoV-2, has recovered, and currently possesses some degree of immunity. Extensive serology testing would help determine the true prevalence of COVID-19, which would aid public health decision-making, release individuals from the constraints of social distancing measures, and eventually restart the economy.

161. Serologic test results can also assist in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

D. Measuring the Effectiveness of Serology Tests

162. The performance of serology tests is described by their "sensitivity," or their ability to identify those with antibodies to SARS-CoV-2 (true positive rate), and their "specificity," or their ability to identify those without antibodies to SARS-CoV-2 (true negative rate).

163. A highly sensitive test will flag almost everyone who has the condition being tested for and will not produce many false-negative results. For example, a test with 90% sensitivity will correctly return a positive result for 90% of people who are positive for the condition they're being tested for, but will return a negative result, *i.e.*, a false-negative, for 10% of the people who should have tested positive. A more specific test will detect only the presence of the specific antibodies of interest and produce few false positive results. However, as the presence of both IgM and IgG vary depending on when the infection occurred, the timing of testing is critical.

164. A test's sensitivity can be estimated by determining whether or not it is able to detect antibodies in blood samples from patients who have been confirmed to have COVID-19 with a nucleic acid amplification test, or NAAT. In some validation studies of these tests, the samples used, in addition to coming from patients confirmed to have COVID-19 by a NAAT, may also be confirmed to have antibodies present using other serology tests.

165. Specificity measures a test's ability to correctly generate a negative result for individuals who do not have the condition being tested for. A high-specificity test will correctly rule out almost everyone who does not have the condition and will not generate many false-positive results. For example, a test with 90% specificity will correctly return a negative result for 90% of people who don't have the condition, but will return a false positive for 10% of the people who do not have the condition and should have tested negative.

166. A test's specificity can be estimated by testing large numbers of samples collected and frozen before SARS-CoV-2 is known to have circulated to demonstrate that the test does not

produce positive results in response to the presence of other causes of a respiratory infection, such as other coronaviruses.

167. Tests are also described by their Positive Predictive Value ("PPV") and Negative Predictive Value ("NPV"). The term "predictive value" refers to the probability of having the condition, given the results of the test. Positive predictive value is the probability that a patient with a positive test result actually has the condition. Negative predictive value is the probability that a person with a negative test result is truly free of the condition.

168. These measures are calculated using a test's sensitivity, specificity, and using an assumption about the percentage of individuals in the population who have antibodies to SARS-CoV-2 (which is called "prevalence" in these calculations). The more sensitive a test, the less likely an individual with a negative test will have the condition and thus the greater the negative predictive value. The more specific the test, the less likely an individual with a positive test will be free from the condition and the greater the positive predictive value.

169. Every test returns some false positive and false negative results. The PPV and NPV help test interpreters understand, given how prevalent individuals with antibodies are in a population, how likely it is that a person who receives a positive result from a test truly does have antibodies to SARS-CoV-2, and how likely it is that a person who receives a negative result from a test truly does not have antibodies to SARS-CoV-2.

170. When the prevalence of preclinical disease is low, the positive predictive value will also be low, even using a test with high sensitivity and specificity. For rarer diseases, a large proportion of those with positive screening tests will inevitably be found not to have the disease upon further diagnostic testing. To increase the positive predictive value of a screening test, a program could target the screening test to those at high risk of developing the disease, based on

considerations such as demographic factors, medical history or occupation. For example, mammograms are recommended for women over the age of forty, because that is a population with a higher prevalence of breast cancer.

171. In response to COVID-19, experts maintain that antibody test manufacturers must have a heightened focus on specificity to reduce the number of instances where individuals falsely believe they have a certain level of immunity and are safe to relax social distancing precautions.

E. Chembio's DPP COVID-19 IgM/IgG Test

172. The Chembio DPP® COVID-19 IgM/IgG System is a single-use rapid immunochromatographic test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in fingerstick whole blood, venous whole blood, serum, or plasma (lithium heparin or EDTA) samples.

173. On April 8, 2020, prior to the EUA grant, Chembio announced that Stony Brook Medicine selected the DPP COVID-19 Test to help identify persons who have recovered from COVID-19 for use in an FDA-approved investigation to determine if convalescent blood plasma from people who have recovered from COVID-19 can help treat hospitalized patients with active COVID-19 infection. The DPP COVID-19 System was used to confirm that patients enrolled in Stony Brook's study had adequate levels of IgG antibodies to make them eligible to donate convalescent plasma. On this news, Chembio stock spiked 8% on April 9, 2020.

174. The DPP COVID-19 Test was granted an EUA by the FDA on April 14, 2020 based on data Chembio stated demonstrated clinical performance estimates of 77.4% positive percent agreement (PPA)/sensitivity for IgM, 87.1% PPA for IgG, 93.5% PPA for combined IgM/IgG, and 94.4% negative percent agreement (NPA)/specificity for combined IgM/IgG. It was also granted regulatory approval by Brazil's Agenica Nacional de Vigilancia Sanitaria, or ANVISA, in April

2020, and gained regulatory clearance from the European Union when it was issued a CE Marking on or about May 4, 2020, enabling its sale in the European community.

175. The DPP COVID-19 IgM/IgG System includes the DPP COVID-19 IgM/IgG Test Devices and the DPP Micro Reader or DPP Micro Reader 2 for use with the DPP COVID-19 IgM/IgG System. The test was made specifically to be read with the DPP Micro Reader or the DPP Micro Reader II, which purportedly minimize human errors due to subjective visual reading of IgM and IgG results.

F. Contradictory Data Available to Chembio Demonstrated the Reduced Accuracy of Its DPP COVID-19 Test

176. After gaining the EUA, the Chembio Defendants knew that the DPP COVID-19 Test would be subject to additional review of its accuracy, specifically the NCI study, and that they would eventually need to take additional steps to maintain its approval from the FDA. The FDA privately informed Chembio by April 29, 2020 that independent evaluation data of Chembio's DPP COVID-19 Test indicated that the test was ineffective and demonstrated a high false positive rate.

177. Only ten days earlier, on April 19, 2020, *The New York Times* described "[a] [m]edical [f]ree-for-[a]ll" with antibody tests where: "More than 90 companies have jumped into the market since the F.D.A. eased its rules and allowed antibody tests to be sold without formal federal review or approval."[3] The article stated that the FDA had received EUA requests from 120 antibody-testing developers, and had only granted formal approval to four so far: Cellex, Ortho Clinical Diagnostics, Chembio, and the Mount Sinai Laboratory. *The New York Times* quoted a doctor from the Association of Public Health Laboratories, who was heartened to see more developers seeking EUAs, describing it as "the gold standard." The article also quoted the FDA

[3] Steve Eder, Megan Twohey, Apoorva Mandavilli, *Antibody Test, Seen as Key to Reopening Country, Does Not Yet Deliver*, THE NEW YORK TIMES (Apr. 19, 2020), https://www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html.

commissioner, Dr. Stephen M. Hahn, who said that "every step we have taken as part of our approach to Covid-19 testing has been a careful balancing of risks and benefits," adding, "We are continuing to learn and adapt based on the real-world experience and data we're seeing."

178. According to the FDA Letter, on April 29, 2020, the FDA reached out to Chembio, stating that new information from three evaluations performed since approval of the EUA demonstrated that Chembio's test performance may be "both inconsistent and lower than that described in [Chembio's] original submission." This was only ten days after *The New York Times* described Chembio's EUA as "the gold standard" and cautioned against inaccurate tests wrongfully allowed into the marketplace. Investors and the public had no reason to believe that Chembio's DPP COVID-19 System was not as accurate as the Company claimed.

179. Until the Revocation, it appeared that Chembio's DPP COVID-19 Test was one of a dwindling number of reputable antibody tests on the market. On May 21, 2020, the FDA announced the removal of 28 other COVID-19 antibody tests from the United States market. The tests were either: (1) voluntarily removed by the test's manufacturer; (2) removed by the FDA because an EUA application was not submitted; or (3) removed because the FDA denied an EUA application. Analysts at Dougherty & Company LLC stated on May 22, 2020 that "[w]e believe more tests will be added to this list, which will effectively reduce competition for [Chembio's] EUA-approved test."

180. Earlier that same week, on May 18, 2020, Chembio announced a strategic supplier partnership with Thermo Fisher Scientific to distribute Chembio's DPP COVID-19 Test in the U.S., which Eberly stated "will significantly increase our commercial footprint."

181. However, in the FDA Letter, the FDA explained that data generated from an independent evaluation of Chembio's device by the Department of Health and Human Services, National Institutes of Health, and the NCI demonstrated an observed PPA of 57.1% for IgM, 78.6%

for IgG, and 82.1% for combined IgM/IgG, which indicates a high false negative rate. The overall NPA was 81.2%, which indicates a high false positive rate. The below chart illustrates the disparity in the data Chembio initially submitted compared to the independent analysis:[4]

Accuracy data on Chembio's antibody test		
	Initially submitted by Chembio	NCI evaluation
IgM sensitivity	77.4%	57.1%
IgM specificity	-	86.2%
IgG sensitivity	87.1%	78.6%
IgG specificity	-	91.2%
Combined sensitivity	93.5%	82.1%
Combined specificity	94.4%	81.2%
Combined PPV	46.8%	18.7%
Combined NPV	99.6%	98.9%
PPV and NPV at 5% prevalence. Source: FDA.		

182. According to the FDA, the performance observed in these additional evaluations was below the clinical performance they generally expect for serology tests to meet the effectiveness and risk/benefit standards for issuance of an EUA. The FDA stated that under its current thinking, based on the totality of scientific evidence currently available to the FDA regarding the clinical performance estimates for serology tests, and under the current circumstances of the public health emergency, clinical agreement data for SARS-CoV-2 antibody tests with 30 positive samples and 75 negative samples generally should demonstrate a minimum combined PPA/sensitivity, of 90%; a

[4] Elizabeth Cairns, *The FDA gets aggressive with Covid-19 antibody tests*, EVALUATE (June 18, 2020), https://www.evaluate.com/vantage/articles/news/policy-and-regulation/fda-gets-aggressive-covid-19-antibody-tests.

minimum NPA/specificity, of 95%; and for tests that report specifically IgM and IgG, a minimum PPA/sensitivity for IgG of 90% and a minimum PPA/sensitivity for IgM of 70%.

183. The FDA also stated that clinical agreement data for SARS-CoV-2 antibody tests with greater than 30 positives and 75 negative samples generally should demonstrate a minimum overall (*i.e.*, IgM/IgG combined) and IgG PPA of 87% with a lower bound of the 95% confidence interval greater than 74.4%, a minimum IgM PPA of 67% with a lower bound of the 95% confidence interval greater than 52.1%, and a minimum NPA of 93% with a lower bound of the 95% confidence interval greater than 87.8%.

184. Notably, the FDA revealed that Chembio submitted supplemental data on April 29, 2020 and May 15, 2020, which did not resolve its concerns regarding the poor clinical performance of Chembio's DPP COVID-19 Test. The FDA also stated that the data provided by Chembio on April 29, 2020 further demonstrated poor performance. As a result, the FDA emailed Chembio on May 22, 2020, explaining its concern that the NCI evaluation data "suggest significant performance concerns with your device, which may put patients at unreasonable risk of harm due to inaccurate results." The FDA also asked Chembio to submit, by May 25, 2020, "information adequate to demonstrate that the health risks posed by your device performing differently than the labeled performance can be adequately mitigated/addressed in a timely manner[,]" and also notified Chembio that if the information it provided did not adequately address the potential risk to patients, the FDA "may take steps and/or request that you take additional actions to protect the public health as appropriate."

185. According to the FDA Letter, Chembio responded on May 24, 2020, stating that an investigation had been performed to better understand and confirm the findings of the NCI evaluation and, based on the results of the investigation, Chembio changed the cut-off for the Micro

Reader II (which was used in the NCI evaluation) from 25 to 35. The cut-off number is used to determine whether COVID-19 antibodies are present in the sample being tested. The Micro Readers interpret the results of the DPP COVID-19 Test by displaying numbers, and the Product Insert instructed users to consider numerical results greater than or equal to 25 as reactive for antibodies (IgG, IgM, and combined), and less than 25 as non-reactive for antibodies. This cut-off is also highlighted in Tables 2 and 8 in the Product Insert.

186. Chembio explained that the re-analysis of the NCI evaluation data using this new cut-off suggested that the specificity of its device could be improved from 81.2% to 93.5% and that the performance of the device with the Micro Reader II with the revised cut-off produces results equivalent to those of the Micro Reader I using the original cut-off that the FDA authorized on April 14, 2020.

187. However, the FDA stated that this change in the cut-off was a ***significant modification*** that affected the sensitivity and specificity of the device, and that such a change must be made in consultation with and the concurrence of the FDA, which Chembio did not obtain. More fundamentally, Chembio's proposed modification of the device did not resolve "the poor clinical performance observed," as demonstrated in the re-analysis of the NCI evaluation results that Chembio provided on May 24, 2020. In the re-analysis, although specificity improved from 81.2% to 93.5%, the sensitivity for IgG decreased from 78.6% to 75.0% and the sensitivities for IgM and combined IgM/IgG were unchanged at 57.1% and 82.1%, respectively.

188. The poor performance of Chembio's DPP COVID-19 Test only became more apparent with time. Compared to the other assays that had been independently checked by or before June 2020, Chembio's Test was at the bottom of all categories, as illustrated below:

Independently evaluated Covid-19 antibody tests with EUAs					
Company	**Test**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Chembio Diagnostic	DPP Covid-19 IgM/IgG	82.1%	81.2%	18.7%	98.9%
Euroimmun (Perkinelmer)	Anti-Sars-CoV-2 Elisa IgG	90.0%	100%	100%	99.5%
Hangzhou Biotest Biotech	RightSign Covid-19 IgG/IgM	100%	100%	100%	100%
Healgen	Covid-19 IgG/IgM	100%	97.5%	67.8%	100%
Commercial tests only. PPV & NPV = positive & negative predictive values. PPV and NPV calculated at 5% prevalence. Source: FDA.					

Materially False and Misleading Statements and Omissions During the Class Period

189. During the Class Period, investors were led to believe that Chembio was able to utilize its diagnostic testing experience to develop an exceptionally accurate serological test for COVID-19 that simultaneously produced speedy results. The Chembio Defendants misrepresented that their DPP COVID-19 serological POC test for the detection of IgM and IgG antibodies was accurate in determining current or past exposure to the COVID-19 virus, that their test provided high sensitivity and specificity, and that it was 100% accurate after 11 days post the onset of symptoms.

190. As a result of the Chembio Defendants' conduct described above, the Chembio Defendants knew or recklessly disregarded that the following statements to Chembio investors were materially false and misleading and/or omitted to state material facts necessary to make those statements not misleading.

A. The March 12 Press Release

191. On March 12, 2020, Chembio announced that the Company had entered into a strategic partnership with LumiraDx, with the goal of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies using its DPP technology. The Company also

issued a separate press release reporting its financial results for the quarter and year ended December 31, 2019, among other things. In pertinent part, defendant Page stated as follows:

> ***"As we look to 2020, we are very excited to partner up with LumiraDx and combine our collective scientific expertise to develop point-of-care tests for COVID-19. We are confident our combined solutions will be the preferred approach for healthcare providers to detect and monitor this pandemic***. In addition, we are pleased to have appointed Richard Eberly as CEO to lead the next phase of Chembio's growth. He is a diagnostics industry veteran who brings to the company years of experience commercializing and growing many product platforms. We are confident we have the right team and technology to extend our leadership in point-of-care diagnostics, grow revenues, and create long-term shareholder value."

192. The statements above in ¶191 expressing confidence that its Test "will be the preferred approach for healthcare providers to detect and monitor this pandemic" were materially false and misleading because the Chembio Defendants misleadingly led investors to believe that Chembio had the ability to quickly and accurately adjust its pre-existing DPP technology to respond to COVID-19, when, in reality, the Chembio Defendants were highly familiar with and knowledgeable about the complex and risky process of verifying testing accuracy, and failed to give investors an accurate impression of the true timeframe required to create an accurate test that would be acceptable to the FDA.

193. Later in the day, Chembio held an investor conference call to discuss its partnership with LumiraDx. During the question and answer session of the investor call, in response to a question about the general timeline for developing a test and gaining approval from the FDA, Defendants Page spoke positively about the Company's approach to creating the Test: "So it's our goal to obviously bring something to the market as soon as possible, but ***we want to bring something that's commercially viable, something that can make a difference and is not just noise in the market***." Defendant Page further stated that "we did not knee-jerk," "we have been very internally focused on understanding what's going on" and "we don't want to be another company out there

that's just making noise. When we come to the table, we want to do something that's significant and it makes the difference and that has some aftermarket impact. . . . "

B. The March 20, 2020 Press Release

194. On March 20, 2020, Chembio circulated a press release titled "Chembio Diagnostics Receives $4 Million Purchase Order from Bio-Manguinhos for Production of DPP COVID-19 IgM/IgG System in Brazil[,]" detailing an order from Bio-Manguinhos, a subsidiary of a company that is largely responsible for meeting the demands of Brazil's national public health system, to purchase approximately $4 million worth of the Company's rapid COVID-19 antibody test.

195. Defendant Esfandiari emphasized the success and performance of the DPP COVID-19 Test as a certainty, stating:

> Recent studies reiterate that both molecular and serological tests are needed to definitively confirm a virus carrier, and ***the strength of our DPP platform technology enabled our team to develop a high quality test for SARS-CoV-2 efficiently and rapidly***. Our serology test will detect the presence of antibodies in blood indicating that a person had an immune response to SARS-CoV-2, regardless of whether symptoms developed from infection or if the infection was asymptomatic.

196. On this news, the Company's stock began to surge in value. In the days leading up to the Company's March 20, 2020 announcement, the Company's stock traded between $2.00 and $3.00 per share. By March 23, 2020, the Company's stock closed at $4.00 per share and then climbed to $5.60 per share by March 27, 2020.

197. The statements above in ¶195 were materially false and misleading because they presented the DPP COVID-19 Test as a strong and high quality test by stating that the DPP platform already "enabled" Chembio "to develop a high quality test for SARS-CoV-2 efficiently and rapidly[,]" which "will" detect the presence of antibodies. In reality, the Chembio Defendants knew, or recklessly disregarded, that the Test was not high quality, that it would not reliably detect the

presence of antibodies, and the trial data testing its accuracy would not support its continued approval by the FDA.

C. The March 31, 2020 Press Release

198. On March 31, 2020, after the market closed, the Company issued a press release titled "Chembio Announces Launch of DPP COVID-19 Serological Point-of-Care Test" that stated the following:

> IgM/IgG Antibody Results in 15 Minutes from a Simple Finger Stick
>
> HAUPPAUGE, N.Y., March 31, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced the U.S. launch of the rapid DPP COVID-19 serological point-of-care test for the detection of IgM and IgG antibodies. These results can be obtained within 15 minutes from a simple finger stick utilizing Chembio's MicroReader 1 and MicroReader 2 analyzers which are produced by Chembio Germany. ***The ability of the DPP platform to provide numerical results can aid clinicians in determining current or past exposure to the COVID-19 virus and monitoring infection progression, while avoiding the human interpretation errors associated with visual readings.***
>
> ***The DPP COVID-19 test detects antibodies in the blood that are produced by the body in response to a novel coronavirus infection. Numerical readings of the IgM and IgG antibodies have the ability to assist clinicians in determining patients who have been exposed to the novel coronavirus, even among patients who exhibit mild to no symptoms.*** Detection of an acute infection phase, as determined by the level of IgM antibodies, helps determine if a patient may still be infectious and could possibility transmit the infection to another person. Further along in the infection progression, the body typically starts to produce IgG antibodies, which increase while IgM levels decrease until eventually only IgG antibodies are present, demonstrating prior infection without the ability to transmit the virus.
>
> "***The results and data from our DPP COVID-19 test can help improve clinical outcomes through the management of individual patients by enabling clinicians to understand the likelihood of past and present infection and to manage populations as a whole as a surveillance test***," stated Richard Eberly, Chief Executive Officer of Chembio. "***Our measured approach has positioned us to offer a viable and sustainable long-term solution for clinicians.*** We expect to begin shipping product in April 2020, and we will continue to work with our partner LumiraDx to provide DPP COVID-19 tests with the ability to scale based upon market demand."
>
> "We are excited that, through diligent collaboration with the FDA, our test will be distributed as authorized by the FDA Notification process under the public health

> emergency guidance issued on March 16, 2020," stated Gail S. Page, Chembio director. "This is another example of Chembio's ability to respond in an expeditious manner to global pandemics with differentiated solutions, as demonstrated previously with Zika and Ebola."
>
> . . .
>
> Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. ***The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes.***

199. The statements above in ¶198 were materially false and misleading because the Chembio Defendants knew or recklessly disregarded that the Company's approach had not "positioned" it to "offer a viable and sustainable long-term solution" since it had already been told by the FDA that the data it used to submit its application for the EUA was inaccurate and not reliable and, as a result, the DPP COVID-19 Test that had been developed was not viable and would not be approved by the FDA as a long term solution.

D. The DPP COVID-19 Test Product Insert Dated April 2, 2020

200. Chembio included false and misleading data in its product insert for the DPP COVID-19 Test, which accompanied the product as it was sent to the public. This information was available to investors at this time and was misleading to the market as well.

Table 1: Positive Agreement of the DPP COVID-19 IgM/IgG System According to Days Post Onset of Symptoms: Endemic Symptomatic Subjects

Days from Symptom Onset to Blood Collection*	Number of Samples	2019-nCoV RT-PCR Result	DPP COVID-19 IgM/IgG System Result as compared to PCR		
			IgM (+)	IgG (+)	IgM (+) and/or IgG (+)
≤6 days	4	Pos	1/4=25%	4/4=100%	4/4=100%
7-10 days	10	Pos	7/10=70%	6/10=60%	8/10=80%
11-14 days	4	Pos	3/4=75%	4/4=100%	4/4=100%
15-18 days	11	Pos	11/11=100%	11/11=100%	11/11=100%
19-21 days	2	Pos	2/2=100%	2/2=100%	2/2=100%
Total	31	N/A	**24/31=77.4%** 95% CI: 60.2% - 88.6%	**27/31=87.1%** 95% CI: 71.1% - 94.9%	**29/31=93.5%** 95% CI: 79.3% - 98.2%

*Development of an antibody response to SARS-COVID-2 can take up to 14 or more days post symptom onset[1].

201. The above table breaks up the data that Chembio submitted to the FDA in connection with the EUA approval process, with 77.4% total IgM, 87.1% IgG, and 93.5% PPA Combined. Broken up by the number of days, the table gives the impression that Chembio's DPP COVID-19 Test was 100% accurate for IgG 11 days from symptom onset to blood collection, 100% accurate for combined IgM and IgG 11 days post symptom onset, and 100% accurate for IgM 15 days post symptom onset.

202. The table referenced above in ¶201 was materially false and misleading because the Chembio Defendants knew or recklessly disregarded that more stringent testing criteria, such as larger sample sizes, is necessary to demonstrate reliable results. The Chembio Defendants previously gained FDA approval for numerous other diagnostic tests, such as its DPP HIV 1/2, DPP Zika, STAT-PAK HIV 1/2, and SURE CHECK HIV 1/2 tests, and were thus aware that results indicating 100% accuracy are not typical. The representations made in the table were also materially false and misleading because the Chembio Defendants were notified by the FDA by April 29, 2020 that these outcomes and data were inaccurate and unreliable. The FDA also informed the Chembio Defendants that additional data it provided to the FDA on April 29, 2020 continued to demonstrate poor performance.

203. The additional tables below were also false and misleading because, for these same reasons, they were not indicative of the DPP COVID-19 Test's true accuracy and performance:

Table 2: Testing Seroconversion Samples from USA using the DPP COVID-19 IgM/IgG System. Results are presented as Reflectance Units where ≥25 is reactive and < 25 is nonreactive

Patient ID #	nCoV-2 PCR Result	Days Between Symptom Onset & Blood Collection	DPP COVID-19 IgM/IgG System		
			IgM (+)	IgG (+)	IgM (+) and/or IgG (+)
022-01	POS	2	7	2	NR
022-02	N/A	11	129	364	R
027-01	POS	15	4	3	NR
027-02	N/A	20	72	260	R
033-01	POS	9	12	3	NR
033-02	N/A	14	172	87	R
057-01	POS	1	4	6	NR
057-02	N/A	5	57	297	R
081-01	POS	10	18	10	NR
081-02	N/A	14	110	107	R
081-03	POS	17	158	360	R
093-01	POS	15	12	7	NR
093-02	N/A	19	7	10	NR
093-03	N/A	22	163	387	R
114-01	POS	9	8	5	NR
114-02	N/A	13	26	131	R
118-01	POS	9	10	10	NR
118-02	N/A	13	36	136	R
118-03	N/A	15	158	363	R
119-01	POS	12	6	5	NR
119-02	N/A	16	11	5	NR
119-03	N/A	19	107	192	R

R = Reactive, NR = Nonreactive; N/A= Not Applicable

Table 3a: Negative Agreement of the DPP COVID-19 IgM/IgG System: Endemic, Symptomatic Subjects

Number of Samples	Origin	2019-nCOV RT-PCR Result	DPP COVID-19 IgM/IgG System results as compared to PCR		
			IgM (-)	IgG (-)	IgM (-) and IgG (-)
2	East Asia	Neg	2/2 = 100%	2/2 = 100%	2/2=100%
39	NY, USA	Neg	38/39 = 97.4%	36/39=92.3%	35/39=89.7%
TOTAL = 41	N/A	N/A	**40/41 = 97.6%** 95% CI: 87.4% - 99.6%	**38/41=92.7%** 95% CI: 80.6% - 97.5%	**37/41=90.2%** 95% CI: 77.5% - 96.1%

Table 3b: Negative Agreement of the DPP COVID-19 IgM/IgG System for Presumed Negative Samples: Endemic, Asymptomatic Subjects

Number of Samples	DPP COVID-19 IgM/IgG System results as compared to expected		
	IgM (-)	IgG (-)	IgM (-) and IgG (-)
49	**49/49=100%** 95% CI: 92.7% - 100.0%	**47/49=95.9%** 95% CI: 86.3% - 98.9%	**47/49=95.9%** 95% CI: 86.3% - 98.9%

Table 4: Negative Agreement of the DPP COVID-19 IgM/IgG System: Non-Endemic, Asymptomatic Subjects

Number of Samples	Origin	Matrix	DPP COVID-19 IgM/IgG System results as compared to expected		
			IgM (-)	IgG (-)	IgM (-) and IgG (-)
25	USA	Plasma	25/25 = 100%	25/25 = 100%	25/25 = 100%
32	Brazil	Plasma	32/32 = 100%	30/32 = 93.4%	30/32 = 93.4%
68		Serum	65/68 = 95.6%	66/68 = 97.1%	63/68 = 92.6%
Total = 125	N/A	N/A	**122/125 = 97.6%** 95% CI: 93.2% - 99.2%	**121/125 = 96.8%** 95% CI: 92.1% – 98.7%	**118/125 = 94.4%** 95% CI: 88.9% – 97.3%

Table 5: Performance of DPP COVID-19 IgM/IgG System with Fingerstick Samples with Confirmed nCoV-2 PCR results: Endemic, Hospital Workers

Number of Samples	nCOV-2 RT-PCR Result	Days Between Symptom Onset and Blood Collection	DPP COVID-19 IgM/IgG System Result as compared to PCR		
			IgM (+)	IgG (+)	IgM (+) and/or IgG (+)
6	Positive	14-17[2]	3/6=50%	6/6=100%	6/6=100%
			IgM (-)	IgG (-)	IgM (-) and IgG (-)
5	Negative	7-17[1]	5/5=100%	5/5=100%	5/5=100%
			Total Agreement		
Total=11	N/A	N/A	**8/11=72.7%** 95% CI: 43.4% – 90.3%	**11/11=100%** 95% CI: 74.1% - 100.0%	**11/11=100%** 95% CI: 74.1% - 100.0%

[1] For 2 samples the day of symptom onset is unknown
[2] For 4 samples the day of symptom onset is unknown

Table 6: DPP COVID-19 IgM/IgG System: Matched venous whole blood, plasma and fingerstick specimens: Endemic, Hospital Workers

	DPP COVID-19 IgM/IgG System		
	Venous Whole Blood (n)	Plasma	Fingerstick
IgM (+) only	3	3/3=100%	3/3=100%
IgG (+) only[1]	7	7/7=100%	7/7=100%
IgG (+) and IgM (+)[2]	5	5/5=100%	4[3]/5=80%
Total	15	**15/15=100%** 95% CI: 79.6% - 100.0%	**14/15=93.3%** 95% CI: 70.2% - 98.8%

[1] nCoV-2 PCR+ results were available for 2 IgG (+) only subjects. The fingerstick results are also presented in Table 5 above.
[2] nCoV-2 PCR+ results were available for and 3 IgM (+) and IgG (+) subjects. The fingerstick results are also presented in Table 5 above.
[3] One specimen was IgM negative. A PCR result was not available for the subject with the discordant (IgM(-)) fingerstick result.

Table 7: Cross Reactivity of the DPP COVID-19 IgM/IgG Assay System

Organisms/Conditions	Number of Samples	DPP COVID-19 IgM/IgG System					
		IgM			IgG		
		POS	NEG	%CR	POS	NEG	%CR
Anti-Dengue virus (IgM and IgG)	5	0	5	0%	0	5	0%
Anti-Chikungunya virus (IgM and IgG)	5	0	5	0%	0	5	0%
Anti-Zika virus (IgM)	5	0	5	0%	0	5	0%
Yellow fever virus post-immunization	5	0	5	0%	0	5	0%
Human coronavirus HKU1[1]	5	0	5	0%	1	4	20%
Human coronavirus 229E	1	0	1	0%	1	0	100%
Human coronavirus NL63	2	0	1	0%	0	2	0%
Human coronavirus OC43	1	0	1	0%	0	1	0%
Influenza A	5	0	5	0%	0	5	0%
Influenza B	5	0	5	0%	0	5	0%
Mononucleosis	5	0	5	0%	0	5	0%

[1]The sample that was IgG-antibody reactive on the DPP COVID-19 IgM/IgG System, was confirmed positive for COVID-19 by a FDA-authorized RT-PCR; a second sample that was found IgM and IgG-antibody non-reactive on the DPP System was also confirmed positive for COVID-19 by the same FDA-authorized RT-PCR.

Table 8: Testing of serially-diluted plasma samples on the DPP COVID-19 IgM/IgG System. Results are presented as Reflectance Units where ≥25 is reactive and <25 is nonreactive.

Dilution	DPP COVID-19 IgM/IgG System – Sample 1		DPP COVID-19 IgM/IgG System – Sample 2	
	IgM Result	IgG Result	IgM Result	IgG Result
1:15	36	290	128	310
1:30	16	197	223	348
1:60	11	66	140	302
1:120	16	66	62	237
1:240	16	32	49	218
1:580	24	15	49	85
1:1160	12	23	14	54
1:2320	17	9	19	74
1:4640	NT	NT	8	21
1:9280	NT	NT	11	11

= R, for Reactive; NT= Not Tested

E. The April 15, 2020 Press Release

204. On April 15, 2020, Chembio issued a press release titled "Chembio Diagnostics Receives Emergency Use Authorization for DPP COVID-19 System for IgG and IgM Antibodies" that stated, as follows:

> First Shipments of the COVID-19 Serological Test have been Released
>
> HAUPPAUGE, N.Y., April 15, 2020 (GLOBE NEWSWIRE) – Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company

> focused on infectious diseases, today announced receipt of Emergency Use Authorization (EUA) for its DPP COVID-19 System. The DPP COVID-19 System is a serological test and analyzer that provides numerical readings for both IgM and IgG levels within 15 minutes from a simple finger stick drop of blood. Both Chembio's Micro Reader 1 and Micro Reader 2 analyzers are compatible with the test.
>
> "We are very pleased with the continued progress our teams are making to address the market demands with our DPP COVID-19 serological system," stated Rick Eberly, Chembio's Chief Executive Officer. ***"The flexibility of having two analyzers and a system that provides high sensitivity and specificity that is generally consistent with the performance of Chembio's other DPP platform tests as part of our offering places us in a unique position to serve a variety of markets***. Additionally, we are pleased to announce that our manufacturing team has produced and shipped our first lots of the COVID-19 Systems, and we look forward to providing further product within the US and abroad."

205. The statements above in ¶204 were materially false and misleading because the Chembio Defendants knew or recklessly disregarded that the data they submitted to the FDA was not meaningful or accurate; accordingly, there was no basis to claim that the DPP COVID-19 System "provides high sensitivity and specificity" and it did not "place[] [Chembio] in a unique position to serve a variety of markets."

F. The May 4, 2020 Conference Call and Press Release

206. On May 4, 2020, the Company reported its financial results for the quarter ended March 31, 2020 and conducted a conference call with investors in which Defendants Eberly and Page participated. During the conference call, Defendant Eberly stated: "***Chembio's product has been reviewed by the FDA after extensive U.S.-based clinical evaluations***. ***The accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies***. ***This is based on our data that was submitted to and reviewed by the FDA for the EUA***." Eberly also represented that:

> "As we touched on previously, ***we expect COVID-19 Systems to drive significant incremental revenue in the future and will be a main driver in the infectious disease vertical.*** There is a very large market that has experienced exponential growth in the past month and continues to unfold many new markets including

> interest from outside historical health care verticals such as companies with back-to-work programs.
>
> We are very optimistic about this opportunity and ***confident in our ability to take significant share in this market and sustain a leadership position for the long term***."
>
> We are taking this opportunity with COVID-19 to pivot the company into a high-value diagnostics company, creating an R&D services vertical and expanding our commercialization strategy to focus on diversifying our products from low-margin tender-driven products to higher-value, higher-margin products.

207. The statements above in ¶206 were materially false and misleading because Defendant Eberly knew or recklessly disregarded that the Chembio Defendants had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance) and, as a result, there was no basis for: (i) claiming that the "accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies;" (ii) any expectation that "COVID-19 Systems [will] drive significant incremental revenue in the future and will be a main driver in the infectious disease vertical;" (iii) any optimism about this opportunity; and (iv) "confiden[ce] in [Chembio's] ability to take significant share in this market and sustain a leadership position for the long term." Moreover, by speaking about the FDA review, Defendant Eberly created a duty to disclose the results of that review, specifically that the Chembio Defendants had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance); Defendant Eberly made no such disclosure.

208. In response to an analyst question during the call about "material revenue acceleration," and what to expect in Q2 and Q3, Eberly stated:

> "So all I can say, Per, is that at this point, the demand is very, very strong. We're in a position right now that we are selling everything that we're manufacturing. So we're pretty optimistic that as we gear up manufacturing -- and I laid out that plan for

> you on the call. We're hopeful that demand will continue to grow. ***So as we -- as our capacity expands, we'll be able to sell everything we make.*** As you know, the uncertainty about the future demand is still a question, but so far, the initial demand from our early launch plans looks very strong."

209. Eberly continued to push the Company's ability to tap into the substantial market demand in a follow-up to a subsequent question, stating: "I think if you've been reading all the information in the press, I mean, people just can't get their hands on enough tests. And so right now, we're seeing demand coming in from pretty much every channel. And so we are – our future strategy is to, as I said, ***expand our distribution strategy to expand our internal selling effort and those channels right now are all open to us***."

210. The statements above in ¶¶208-209 discussing the strong demand for the Test were materially false and misleading because the Chembio Defendants knew or recklessly disregarded but failed to disclose that there was an increased risk that the EUA would be revoked and/or that Chembio would not receive long term FDA approval for the Test, as they had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance).

211. In the same call, an analyst from Craig-Hallum Capital Group LLC, pointed out that "the relative noise out there about antibody testing and still the relatively small number of EUAs granted, 10, 11 of them in the serological realm. As far as I can tell, you're one of a few rapids. You're the only numerical result. You're the only finger-stick[,]" and asked: "How difficult is it to get that message out when there's so much other noise about other tests and maybe some other concerns about quality of other antibody tests that are out there? And does a CLIA Waiver makes sense for you at some point here given what looks to be a relatively easy-to-use system?" In response, Defendant Page stated:

> I think it's important that the FDA has been tightening down on those that have done the FDA notification of vaccine guidance, I think, was released as -- latest today. And I think for a lot of those people on the call that talked to me early on, one of the things we talked about was that there was an awful lot of noise in the market but it would [lead] itself out.
>
> I think now you're seeing dependent on swing back. I think there are 3 in our category that have the EUA. ***And as you said, we're the only one with finger-stick. So I think we're very well positioned. I think you'll see a lot of those fall out.*** The indications today were they had 10 days to file for their Emergency Use Authorization.
>
> ***So I think that's really going to change and get rid of a lot of the noise that's in the market. So I think that's very beneficial for people like us that we may not necessarily be first, but we intend to be the best in the market***.

212. The statements above in ¶211 that Defendant Page thinks the Company is "very well positioned" and that the tightening down by the FDA on inaccurate and unreliable tests is "very beneficial for people like us" were materially false and misleading and lacking in a reasonable basis at all relevant times because she knew or recklessly disregarded that the FDA had already told the Chembio Defendants that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance) and, as a result, there was an increased risk that Chembio's EUA would be revoked and/or that Chembio would not receive long term FDA approval for the Test. Moreover, by speaking about the tightening down by the FDA on inaccurate and unreliable tests, Defendant Page created a duty to disclose that the Chembio Defendants had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance); Defendant Page made no such disclosure.

213. In further support, Eberly added: "I would just add that we took a very measured approach in our clinical studies, which is why we got the finger-stick claim in our studies. So we didn't race to the FDA notification process. We took a measured approach, made sure our clinical

valuations were strong, the data looked good. And we had differentiated features in the product that allows us to roll it out into a diverse market."

214. The statements above in ¶213 by Defendant Eberly that the Company "took a very measured approach" in its clinical studies, "didn't race to the FDA notification process" and "made sure our clinical valuations were strong, the data looked good" were materially false and misleading and lacking in a reasonable basis at all relevant times because he knew or recklessly disregarded that the FDA had already told the Chembio Defendants that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance), *i.e.*, that its clinical valuations were, in fact, not strong and the data did not look good. Moreover, by speaking about Chembio's EUA application process, clinical evaluations, and data, Defendant Eberly created a duty to disclose that the Chembio Defendants had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance); Defendant Eberly made no such disclosure.

215. The Company also issued a press release on May 4, 2020, regarding the financial results for the quarter ended March 31, 2020, that stated, in part, the following:

Recent Accomplishments & Highlights

- **Attained FDA Emergency Use Authorization for the DPP COVID-19 IgM/IgG System serological test**
- **Announced the U.S. launch and shipments to customers of the DPP COVID-19 System**
- Selected by Stony Brook Medicine as the testing solution to identify COVID-19 survivors for study on COVID-19 convalescent plasma therapy
- Received a $4.0 million purchase order from Bio-Manguinhos for our DPP COVID-19 System . . . .

> During the first quarter, we refocused our business strategy to address the escalating need for COVID-19 diagnostic tests. In a short period of time, we developed a COVID-19 serological testing system, **received FDA Emergency Use Authorization** and began shipping tests to customers in the United States and Brazil in April. Our differentiated testing system offers numerical discrete detection of both IgM and IgG antibodies in approximately 15 minutes from a fingerstick. Then, in approximately 15 seconds, the DPP COVID-19 System reads the test to provide numerical results using the portable Micro Reader analyzers that are engineered and produced by our wholly owned subsidiary in Germany. Numerical results reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests," said Gail Page, Chembio's Executive Chair of the Board. "We are proud to be serving the needs of clinicians and the broader healthcare community in this time of crisis.
>
> It has been an extremely productive first few weeks in my new role as CEO. Amid these challenging circumstances, the skill and hard work of this team has ***enabled a successful strategic pivot as we prioritize manufacturing and commercialization of our DPP COVID-19 System***," said Richard Eberly, Chembio's Chief Executive Officer. "Through efficient use of our resources and technical ability, we are scaling production of these tests due to the strong demand we are experiencing. ***We believe the features and benefits offered by our DPP COVID-19 System will make it a preferred solution***."

216. The statements above in ¶215 that the Company made "a successful strategic pivot" and that Defendant Eberly believes the DPP COVID-19 System will be a "preferred solution" were materially false and misleading and lacking in a reasonable basis at all relevant times because the Chembio Defendants knew or recklessly disregarded that the FDA had already told them that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance) and, as a result, there was an increased risk that Chembio's EUA would be revoked and/or that Chembio would not receive long term FDA approval for the Test. Moreover, by stating that Chembio had received the EUA, the Chembio Defendants created a duty to disclose that they had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance); the Chembio Defendants made no such disclosure.

G. The May Offering

217. On May 8, 2020, the Registration Statement for the May Offering became effective. As detailed above in ¶¶68-81, the Registration Statement made numerous representations regarding the accuracy and prospects of the DPP COVID-19 Test. These statements were materially false and misleading because, as described below in ¶¶220-222 and elsewhere herein, the Chembio Defendants knew or recklessly disregarded that the FDA had already told the Chembio Defendants that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance). Moreover, by speaking about Chembio's DPP COVID-19 Test, the Chembio Defendants created a duty to disclose that they had already been told by the FDA that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance); the Chembio Defendants made no such disclosure.

H. The May 11, 2020 Press Release

218. On May 11, 2020, the Company issued a press release titled "Chembio Diagnostics Announces Closing of Public Offering of Common Stock" that stated the following:

> HAUPPAUGE, N.Y., May 11, 2020 (GLOBE NEWSWIRE) – Chembio Diagnostics, Inc. (Nasdaq: CEMI) ("Chembio"), a leading point-of-care diagnostic company focused on infectious diseases, announced today the closing of its previously announced public offering of 2,619,593 shares of its common stock, which included 281,125 shares issued pursuant to the partial exercise by the underwriters of their option to purchase additional shares, at a public offering price of $11.75 per share for gross proceeds of approximately $30.8 million. All shares of common stock sold in the offering were offered by Chembio.

I. The May 18, 2020 Press Release

219. On May 18, 2020, the Company issued a press release titled "Chembio Diagnostics Announces US Distribution Agreement to Expand Reach of DPP COVID-19 Serological Test with Thermo Fisher Scientific's Healthcare Channel" that stated the following:

> HAUPPAUGE, N.Y., May 18, 2020 (GLOBE NEWSWIRE) – Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced it has signed a multi-year, non-exclusive agreement with Thermo Fisher Scientific's healthcare channel, to distribute Chembio's DPP COVID-19 System in the United States. ***The DPP COVID-19 System is a rapid serological test and analyzer that provides numerical readings for both IgM and IgG antibody levels within 15 minutes from a finger stick drop of blood.*** The DPP COVID-19 System can include either Chembio's Micro Reader 1 or Micro Reader 2 analyzer.
>
> "We are pleased to announce our strategic supplier partnership with the Fisher Healthcare channel, ***which will significantly increase our commercial footprint by providing access to thousands of hospital and physician office moderately complex labs across the country***," stated Rick Eberly, Chembio's President and Chief Executive Officer. "We have initiated a comprehensive training and marketing program for the Fisher Healthcare channel sales team, in order to expand the targeted coverage for this important segment of the market as soon as possible."

220. The statements referenced above in ¶219 that the Company's strategic partnership "will significantly increase [its] commercial footprint by providing access to thousands of hospital and physician office moderately complex labs across the country" were materially false and misleading and lacking in a reasonable basis at all relevant times because the Chembio Defendants knew or recklessly disregarded and failed to disclose that the FDA had already told them that the data used to submit Chembio's application for the EUA was inaccurate and not reliable (and the additional supplemental data submitted by Chembio also demonstrated poor performance) and, as a result, there was an increased risk that Chembio's EUA would be revoked and/or that Chembio would not receive long term FDA approval for the Test. Moreover, by discussing the Test and the results that it provides, the Chembio Defendants created a duty to disclose that they had already been

told by the FDA that the Test results had not be shown to be reliable or accurate; the Chembio Defendants made no such disclosure.

221. The FDA also emailed Chembio on May 22, 2020, expressing its concern that the NCI evaluation data suggested that the DPP COVID-19 Test's performance concerns may put patients at unreasonable risk, and asked Chembio to submit additional information by May 25, 2020. The FDA notified Chembio that if the information it provided did not adequately address the potential risk to patients, it "may take steps and/or request that you take additional actions to protect the public health as appropriate."

222. Chembio conducted an investigation into the NCI findings and responded to the FDA on May 24, 2020. Unable to refute the NCI results, the Chembio Defendants attempted to change the cut-off for the Micro Reader II to increase the specificity of its device, in a last ditch effort to maintain its EUA. The FDA refuted this attempt to change widely-applicable testing methodology, stating that the change would be a significant modification which would require FDA approval, and that even if implemented, the DPP COVID-19 Test still would not meet the EUA criteria for sensitivity and specificity.

223. The Company's misrepresentations/omissions ultimately drove the Company's stock from a closing price of $3.10 per share on March 11, 2020, to a Class Period high of $15.54 per share on April 24, 2020, an increase of more than 400%.

J. The Truth Is Revealed When the FDA Revokes Chembio's EUA for the DPP COVID-19 IgM/IgG System

224. Investors learned the truth for the first time when the FDA disclosed that it had revoked Chembio's EUA for the DPP COVID-19 IgM/IgG System. On June 16, 2020, after the market closed, the FDA issued a press release disclosing that it had revoked its EUA for the Company's DPP COVID-19 IgM/IgG System:

> Today, the U.S. Food and Drug Administration revoked the emergency use authorization (EUA) of the Chembio Diagnostic System, Inc. (Chembio) DPP COVID-19 IgM/IgG System, a SARSCoV-2 antibody test, **due to performance concerns with the accuracy of the test**. Antibody tests, a type of serological test, can help provide information on a person's and population's exposure to COVID-19.
>
> Since the beginning of the COVID-19 public health emergency, the FDA has balanced the urgent need for access to diagnostic and antibody tests with providing a level of oversight that helps to ensure accurate tests are being deployed," said Jeff Shuren, M.D., director of FDA's Center for Devices and Radiological Health. "By continuing to monitor authorized tests and emerging scientific evidence, we are able to make changes when appropriate – **including taking action when a test's benefits no longer outweigh its risks**. Through these efforts, we are able to help assure that FDA-authorized tests meet the needs of the American public."
>
> The Chembio antibody test was one of the first antibody tests authorized by the FDA during the COVID-19 public health emergency. At the time of authorization, **based on the information that Chembio submitted to the FDA at that time**, the agency concluded that the test met the statute's "may be effective" standard for emergency use authorization, and that the test's known and potential benefits outweighed its known and potential risks.
>
> As the FDA has learned more regarding the capability for performance of SARS-CoV-2 serology tests during the pandemic, and what performance is necessary for users to make well-informed decisions—through both the continued review and authorization of serology tests as well as through a research partnership with the National Institutes of Health's National Cancer Institute (NCI)— the FDA was able to develop general performance expectations for these tests, which are listed in our serology templates.
>
> **Data submitted by Chembio as well as an independent evaluation of the Chembio test at NCI showed that this test generates a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device. Under the current circumstances of the public health emergency, it is not reasonable to believe that the test may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the test outweigh the known and potential risks of the test, including the high rate of false results.** Moreover, the risk to public health from the false test results makes EUA revocation appropriate to protect the public health or safety. As such, the FDA decided to revoke the emergency use authorization of the Chembio test, and this test may not be distributed.

225. On June 17, 2020, the Company filed a report with the SEC on Form 8-K that acknowledged receipt of the FDA's June 16, 2020 letter and stated, in part, the following:

> On June 16, 2020, we received a letter from the U.S. Food and Drug Administration, or FDA, notifying us that the FDA was revoking the Emergency Use Authorization, or EUA, granted in April 2020 with respect to our DPP COVID-19 System, which consists of our serological test for COVID-19 and one of our Micro Reader analyzers. As a result of this decision by the FDA, we may no longer distribute the DPP COVID-19 System. . . .
>
> In its letter of June 16, 2020, the FDA stated that it had decided to revoke the EUA for the DPP COVID-19 System due to performance concerns regarding the sensitivity and specificity of our test system. . . .
>
> We intend to continue working with the FDA with respect to the modification of the DPP COVID-19 System and of the revocation of the EUA for our test system.

226. The FDA revocation revealed previously undisclosed efficacy issues with Chembio's test, and materialized the previously concealed risk that the FDA would reject the test because of the efficacy issues.

227. As a result of the disclosure of the FDA Letter, Chembio shares declined from a closing price on June 16, 2020 of $9.93 per share to close at $3.89 per share on June 17, 2020, a decline of $6.04 per share, or over 60%, on heavier than usual volume of over 25 million shares traded. Chembio stock started reacting to the news after-hours on June 16, 2020, falling as low as $6.85 per share, with the fallout continuing into the market session the next day.

228. Also on June 17, 2020, *Bloomberg* published a report titled "FDA Reversal on Chembio Antibody Test Sends Stock Down 63%" that noted that, in light of the FDA revocation of the Company's EUA, five analysts downgraded Chembio stock.[5]

229. Other media outlets also connected the stock decline to the revelations in the FDA disclosure. Business site *Smarter Analyst* wrote that Chembio stock "plunged" "after the FDA said that there were performance concerns with the accuracy of Chembio's SARS-CoV-2 antibody test."

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[5] Cristin Flanagan, *FDA Reversal on Chembio Antibody Test Sends Stock Down 63%*, BLOOMBERG (June 17, 2020), https://www.bloomberg.com/news/articles/2020-06-17/fda-reversal-on-chembio-test-sounds-an-alarm-for-canaccord

Business site *Benzinga* wrote that while Chembio had "rallied nicely following the launch of its rapid DPP COVID-19 serological point-of-care test" the stock was "pulling back sharply" related to FDA action "premised" "on performance concerns with the accuracy of the test."

230. The FDA's revocation of the COVID-19 Test EUA forced the Company to recall all existing unused DPP COVID-19 Tests that already had been shipped to customers in the United States. Chembio's inability to continue to sell the DPP COVID-19 Test in the United States disrupted the Company's expansion plan to dedicate all of its production lines to producing the Test.

231. As a result of the Chembio Defendants' false and misleading statements of fact and omissions of material facts, other wrongful acts and omissions as alleged herein, and the precipitous decline in the market value of the Company's common stock, Lead Plaintiffs and other Exchange Act Class members have suffered significant losses and damages.

AFTER THE CLASS PERIOD

232. Chembio submitted a new DPP SARS-CoV-2 IgM/IgG test to the FDA in September 2020. In December 2020, Chembio revealed in an SEC filing that its EUA submission for a new COVID-19 antibody test was deprioritized by the FDA and that as a result, the FDA will not review Chembio's EUA submission for the test. The FDA declined to review the request because it would have "relatively limited impact on testing accessibility or testing capacity[.]" In response, Chembio stated that: "We intend to work with the FDA to seek to establish priority for our IgM/IgG EUA, based on our belief that the DPP SARS COV-2 IgM/IgG with DPP Micro Reader would increase testing accessibility[.]"

The Chembio Defendants Violated Regulation S-K

233. As discussed above, pursuant to Item 303 of SEC Regulation S-K, 17 C.F.R. §229.30 ("Item 303") and the SEC's related interpretive releases thereto, an issuer is required to disclose known trends, uncertainties or risks that have had, or are reasonably likely to have, a materially

adverse impact on net sales or revenues, or income from continuing operations. Such disclosure is required by an issuer in regulatory reports.

234. The SEC issued an interpretive release on Item 303 on or about May 18, 1989, stating:

> Required disclosure is based on currently known trends, events, and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.
>
> * * *
>
> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

235. Item 303 required Chembio's regulatory filings to describe "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. §229.303(a)(3)(ii). Similarly, Item 303 required Chembio's regulatory reports to disclose events that Chembio knew would "cause a material change in the relationship between costs and revenues" and "any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected." 17 C.F.R. §229.303(a)(3)(i), (ii).

236. By April 29, 2020, the Chembio Defendants knew that the FDA had already communicated to them data underlying Chembio's EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System. As the Class Period progressed, the FDA made multiple requests for additional information from Chembio, each time expressing dissatisfaction with the information provided. As such, whether the FDA would continue to allow the EUA for the DPP COVID-19 System based on the data and application submitted (as

well as the supplemental submissions of information) was a known uncertainty that was then having, and would continue to have, an unfavorable impact on the Company's revenues and income from continuing operations, and was therefore required to be disclosed but was not.

237. In addition, Item 105 of SEC Regulation S-K, 17 C.F.R. §229.105, required a discussion of the most significant factors that made an investment in the company risky or speculative and that each risk factor adequately describe the risk.

238. The Chembio Defendants failed to disclose there was an increased risk that Chembio's EUA for the DPP COVID-19 System could be revoked and any long term application for approval denied because the FDA had told Chembio that data underlying Chembio's EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System (and the supplemental information submitted demonstrated poor performance). Because this risk was not disclosed, the Chembio Defendants violated Item 105.

ADDITIONAL SCIENTER ALLEGATIONS

239. In addition to the facts alleged above, the following facts provide additional indicia of scienter: (i) the misrepresentations alleged herein involved the most important aspect of Chembio's business and operations; and (ii) the misrepresentations alleged herein resulted in unprecedented business opportunities for Chembio, which the Chembio Defendants leveraged in their favor.

The Core Importance of Chembio's DPP COVID-19 Test

240. The adverse developments at issue impacted the most central aspect, or the core, of the Company's business, operations, and revenue. Due to the Company's prior financial struggles, described above, Chembio was particularly incentivized to take advantage of the unprecedented demand for COVID-19 tests, and quickly adapted its pre-existing DPP technology to its DPP COVID-19 Test, effectively abandoning its other "legacy products."

241. During the Class Period, the Company was entirely focused on the DPP COVID-19 Test. As described above, the Registration Statement stated:

> We refer to our infectious disease products, other than the DPP COVID-19 System, as our legacy products. We expect to generate an immaterial amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the manufacture and commercialization of the DPP COVID-19 System.

242. The Registration Statement also detailed major operational shifts to accommodate this change in business strategy:

> In connection with obtaining the EUA for the DPP COVID-19 System, we have begun the process of shifting substantially all of our test manufacturing capacity to the DPP COVID-19 System. This shift included investment totaling approximately $0.8 million to increase tooling capacity, advance our automated manufacturing, and begin recruiting additional workers to expand capacity and supplement absenteeism associated with employee self-quarantines as the result of the COVID-19 pandemic.

243. As a result, the DPP COVID-19 Test's performance and prospects were highly material to Chembio's business during the Class Period, and indeed the Company represented to investors that all of its products besides the Test had an "immaterial" impact on Chembio's financial performance and business prospects. If Chembio was no longer able to commercialize its main product in the United States, it would have a material impact on the Company's profits and operations, for the simple reason that the DPP COVID-19 Test was, at least during the relevant time period, the Company's sole focus. Indeed, as detailed above, during the Class Period, Chembio shifted nearly all of its manufacturing and product marketing to support the commercialization of the DPP COVID-19 Test.

244. The Chembio Defendants also had control over Chembio's FDA submissions and communications, and repeatedly emphasized the Company's expertise and progress in developing and commercializing the DPP COVID-19 Test.

245. During the Class Period, the Chembio Defendants' communications to the public almost exclusively concerned the DPP COVID-19 Test. On April 18, 2020, Defendant Page, as

interim CEO of the Company, even appeared on "Fox and Friends" to promote the product. She opined on how Chembio "took a very measured approach" and how developing the DPP COVID-19 Test was a "natural progression" for the Company, and also displayed expertise on the Test's ability to detect IgM and IgG antibodies.

246. The analysts following Chembio confirmed the paramount importance of the DPP COVID-19 Test and the sole focus of Chembio developing, marketing, and selling the Test during the Class Period. For instance, Craig-Hallum reduced their stock price target for the Company threefold (from $24/share to $8/share) following the revelation of the FDA Letter, "sharply lower[ing]" revenue and "dramatically" cutting forecasts. Canaccord Genuity reduced its price target by more than threefold, from $22 to $7, noting that its entire "Buy" thesis for the security was Chembio's ability to "generate sales of its [DPP COVID-19 Test]."

247. Given the incredible importance of the DPP COVID-19 Test to the Company's financial performance, there is no doubt that the Chembio Defendants would immediately have been aware of any concerns raised by the FDA regarding the Test.

The Unprecedented Benefits of the DPP COVID-19 Test for Chembio's Business

248. Prior to the Class Period, Chembio's business of developing, manufacturing, and commercializing POC diagnostic tests was not reaping substantial rewards. According to the 2018 and 2019 Forms 10-K, Chembio incurred an operating loss each year from 2014 through 2019. However, the Chembio Defendants' misrepresentations and omissions concerning developing and marketing the DPP COVID-19 Test greatly increased Chembio's share price, driving the Company's stock from a closing price of $3.10 per share on March 11, 2020 to a Class Period high of $15.54 per share on April 24, 2020, an increase of more than 400%.

249. After announcing its partnership with LumiraDx and expressing certainty on its ability to commercialize its DPP COVID-19 Test, Chembio's shares increased during after-hours

trading from $3.10 per share at close on March 11, 2020, to an opening share price of $4.19 on March 12, 2020. The Company's stock also surged in value after its announcement on March 20, 2020 that Bio-Manguinhos placed a purchase order for approximately $4 million worth of the Company's rapid COVID-19 antibody test. In the days leading up to this announcement, the Company's stock traded between $2.00 and $3.00 per share, and by March 23, 2020, the Company's stock closed at $4.00 per share and then climbed to $5.60 per share by March 27, 2020. Additionally, Chembio's announcement on April 2, 2020, that it would embark on the U.S. launch of its DPP COVID-19 Test, sent shares 40% higher on about 100x typical daily share volume.

250. Defendants took advantage of this inflated share price by conducting the May Offering at an artificially inflated price. The Registration Statement stated: "We estimate we will receive net proceeds from this offering of $25.3 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares is exercised in full, we estimate our net proceeds will be $29.1 million." Chembio's cash and cash equivalents totaled $11.2 million at March 31, 2020, and would have been $36.5 million after giving effect to the receipt of the net proceeds from the May Offering, or $40.3 million if the underwriters' option to purchase additional shares was exercised in full.

251. The Company stated that it intended to use the net proceeds "to support the refocus of our business strategy, including the manufacturing and further commercialization of the DPP COVID-19 System, to expand our sales force to support growth, to increase our manufacturing capacity and for other general corporate purposes."

252. As described above, prior to the May Offering, Defendants already knew that the DPP COVID-19 Test was not as accurate as previously expressed to the FDA, but reiterated the data to investors in the Registration Statement regardless without disclosing that they had been notified by

the FDA by April 29, 2020 that new information from three evaluations performed since the initial EUA grant on April 14, 2020 demonstrated that Chembio's test performance may be "both inconsistent and lower than that described in your original submission." Data generated from an independent evaluation of Chembio's device by the Department of Health and Human Services, National Institutes of Health, and the NCI demonstrated that relevant measures of the test's accuracy fell below the percentages deemed acceptable by the FDA.

253. Chembio's submissions of additional data to the FDA on April 29, 2020 and May 15, 2020, which the FDA stated did not resolve its concerns regarding the poor clinical performance of Chembio's DPP COVID-19 Test and even provided further indication of poor performance, were in close proximity to the May Offering. Maintaining the appearance of their most important product's viability allowed the Chembio Defendants to maximize the gains associated with the May Offering, and the Chembio Defendants had ample motivation to conceal this information.

254. Additionally, gaining EUA approval for the DPP COVID-19 Test aided Chembio in obtaining regulatory approval in foreign countries, which the Company was able to retain even after the EUA was revoked. In April 2020, Chembio gained approval for emergency use by Brazil's Agência Nacional de Vigilância Sanitária, or ANVISA, and later gained a CE Marking from the European Union in early May 2020.

255. As alleged herein, the Chembio Defendants acted with scienter in that they knew the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents and in actions intended to manipulate the market price of Chembio common stock as primary violations of the securities laws.

256. As set forth herein in detail, the Chembio Defendants, by virtue of their receipt of information reflecting the true facts regarding Chembio, their control over, and/or receipt or modification of, Chembio's allegedly materially misleading misstatements, and/or their associations with the Company that made them privy to confidential proprietary information concerning Chembio, participated in the fraudulent scheme alleged herein.

257. As a result, the Chembio Defendants knew, or were reckless in not knowing, of the undisclosed facts herein.

Corporate Scienter

258. The allegations above also establish a strong inference that Chembio as an entity acted with corporate scienter throughout the Class Period, as its officers, management, and agents, including, but not limited to, the Officer Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the concerns raised by the FDA from the investing public. Indeed, the FDA would have only communicated regarding these "bet the company" issues with senior individuals at Chembio who would have been in a position to establish Chembio's scienter, such as Dr. Louise M. Sigismondi, Research and Development Director of Regulatory Affairs at Chembio Diagnostic Systems, who received the FDA Letter. By concealing these material facts from investors, Chembio maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

259. Moreover, given the extensive communications that the Officer Defendants had with analysts and investors, including the Funds, and the detail of their representations regarding the

Test's specific numerical performance, each either made him or herself aware of the Company's and FDA's actual (but undisclosed) findings and diagnostic results with respect to the Test or had no factual basis to make such specific quantitative statements. In either event, the Officer Defendants were at least reckless with respect to the truth, and their scienter is imputable to the Company.

LOSS CAUSATION/ECONOMIC LOSS

260. During the Class Period, as detailed herein, the Chembio Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Chembio common stock and operated as a fraud or deceit on purchasers of Chembio common stock. When the truth about Chembio's misconduct was revealed, the value of Chembio common stock declined significantly as the prior artificial inflation was removed from the price of the stock.

261. As discussed above, investors learned the truth when the FDA disclosed that it had revoked Chembio's EUA for the DPP COVID-19 Test. Chembio publicly acknowledged receipt of the FDA Letter on June 17, 2020, and as a result of the disclosure, Chembio shares declined from a closing price on June 16, 2020 of $9.93 per share to close at $3.89 per share on June 17, 2020, a decline of $6.04 per share, or over 60%, on heavier than usual volume of over 25 million shares traded.

262. The decline in the price of Chembio common stock was the direct result of the nature and extent of the Chembio Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the price declines negate any inference that the losses suffered by Lead Plaintiffs and other members of the Exchange Act Class were caused by changed market conditions, macroeconomic or industry factors or company-specific facts unrelated to the defendants' fraudulent conduct.

263. The economic loss, *i.e.*, damages, suffered by Lead Plaintiffs and other Exchange Act Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of

Chembio common stock and the subsequent significant decline in the value of Chembio common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

264. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by Lead Plaintiffs and other Exchange Act Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Chembio's business, operations and financial condition, as alleged herein. Throughout the Class Period, the Chembio Defendants issued materially false and misleading statements and omitted material facts necessary to make the Chembio Defendants' statements not false or misleading, causing the price of Chembio common stock to be artificially inflated at all relevant times. Lead Plaintiffs and other Exchange Act Class members purchased Chembio common stock at those artificially inflated prices, causing them to suffer the damages detailed herein when the truth was revealed.

APPLICABILITY OF THE PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

265. Lead Plaintiffs and the other members of the Exchange Act Class will rely, in part, upon the presumption of reliance established by the fraud-on-the-market presumption of reliance in that, among other things:

(a) the Chembio Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) Chembio common stock traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Chembio common stock; and

(e) Lead Plaintiffs and the other members of the Exchange Act Class purchased Chembio common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts began to be disclosed, without knowledge of the misrepresented or omitted facts.

266. At all relevant times, the market for Chembio common stock was an efficient market for the following reasons, among others:

(a) Chembio's common stock trades on the NASDAQ;

(b) According to the Company's May 6, 2020 Form 10-K, there were more than 17,548,910 shares of Chembio common stock outstanding as of April 29, 2020, representing a very broad and active trading market;

(c) Chembio filed public reports with the SEC;

(d) Chembio regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on national circuits of major newswire services, the Internet, and other wide-ranging public disclosures;

(e) Chembio was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace; and

(f) Unexpected material news about Chembio was rapidly reflected in and incorporated into Chembio common stock prices during the Class Period.

267. Because Chembio is a publicly traded company, the Chembio Defendants knew, understood and had reason to expect that: (1) their misstatements would artificially inflate the price of Chembio common stock; (2) investors would rely on the price of Chembio common stock as

reflecting accurate information known to Chembio and its executives; and (3) their misstatements and omissions would induce Lead Plaintiffs and/or their agents and other Exchange Act Class members to purchase Chembio common stock during the Class Period.

268. As a result of the foregoing, the market for Chembio common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of Chembio common stock. Under these circumstances, all purchasers of Chembio common stock during the Class Period suffered similar injury through their purchase of Chembio common stock at artificially inflated prices, and a presumption of reliance applies.

269. Further, Lead Plaintiffs' and other Exchange Act Class members' reliance will be proved on a class-wide basis through common, circumstantial evidence that Lead Plaintiffs would not have purchased Chembio common stock but for the Chembio Defendants' uniform misrepresentations and omissions about Chembio's DPP COVID-19 Test.

270. Lead Plaintiffs are also entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein are predicated in part upon omissions of material fact for which there was a duty to disclose. Specifically, Lead Plaintiffs are entitled to a presumption of reliance throughout the Class Period because, as more fully alleged above, the Chembio Defendants misrepresented and failed to disclose material information regarding Chembio's DPP COVID-19 Test.

NO SAFE HARBOR

271. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged. Many of the statements herein were not identified as "forward-looking statements" when made. Alternatively, to the extent that there were any forward-looking statements, no meaningful cautionary language identified important

factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. If the statutory safe harbor indeed applies to any forward-looking statements pleaded herein, the Chembio Defendants are liable because at the time each forward-looking statement was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

CLASS ACTION ALLEGATIONS

272. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all persons who purchased or otherwise acquired Chembio securities on the open market between March 12, 2020 and June 16, 2020, inclusive (the "Class Period"). This class of investors asserts claims only for violations of Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b) and 78t(a), and Rule l0b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5, as well as Section 20(a) of the Exchange Act.

273. The members of the Exchange Act Class are so numerous that joinder of all members is impracticable. While the exact number of Exchange Act Class members is unknown to Lead Plaintiffs at the present time, Lead Plaintiffs believe that there are hundreds of members of the Exchange Act Class located throughout the United States. As of April 29, 2020, Chembio had over 17 million shares of common stock outstanding, which were actively traded on the NASDAQ in an efficient market.

274. Lead Plaintiffs' claims are typical of the claims of Exchange Act Class members. Lead Plaintiffs and all members of the Exchange Act Class have sustained damages because of the Chembio Defendants' unlawful activities alleged herein. Lead Plaintiffs have retained counsel competent and experienced in class and securities litigation and intend to pursue this action vigorously. The interests of the Exchange Act Class will be fairly and adequately protected by Lead

Plaintiffs. Lead Plaintiffs have no interests which are contrary to or in conflict with those of the Exchange Act Class that they seek to represent.

275. Common questions of law and fact exist as to all members of the Exchange Act Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the Exchange Act Class are:

(a) whether the Chembio Defendants violated the Exchange Act;

(b) whether the Chembio Defendants omitted and/or misrepresented material facts;

(c) whether the Chembio Defendants knew or recklessly disregarded that their statements were false;

(d) whether the price of Chembio common stock was artificially inflated during the Class Period; and

(e) the extent of and appropriate measures of damages.

276. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Lead Plaintiffs know of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

COUNT IV

For Violations of §10(b) of the Exchange Act and Rule 10b-5
Against the Chembio Defendants

277. MERS and the Funds repeat and reallege the above allegations as if fully set forth herein.

278. During the Class Period, the Chembio Defendants disseminated or approved false statements, which they knew or recklessly disregarded were misleading in that they contained

misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

279. The Chembio Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon MERS, the Funds, and others similarly situated in connection with their purchases of Chembio common stock during the Class Period.

280. MERS, the Funds, and the Exchange Act Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Chembio common stock and suffered losses when the relevant truth was disclosed. MERS, the Funds, and the Exchange Act Class would not have purchased Chembio common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by the Chembio Defendants' misleading statements and omissions.

COUNT V

For Violations of §20(a) of the Exchange Act
Against the Officer Defendants

281. MERS and the Funds repeat and reallege the above allegations as if fully set forth herein.

282. The Officer Defendants acted as controlling persons of Chembio within the meaning of Section 20(a) of the Exchange Act. By reason of their positions as officers and directors of

Chembio, and their ownership of Chembio securities, the Officer Defendants had the power and authority to, and did, cause Chembio to engage in the wrongful conduct complained of herein.

283. As a result of their positions of control and authority as senior officers and their culpable participation, as alleged above, the Officer Defendants had the power to influence and control, and did, directly or indirectly, influence and control the decision making of the Company, including the content and dissemination of the various statements Lead Plaintiffs contend were false and misleading herein. The Officer Defendants were able to, and did, control the content of submissions to the FDA and other regulatory bodies, and had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading before and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

284. By reason of such conduct, the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act.

285. As a direct and proximate result of the Officer Defendants' wrongful conduct, MERS, the Funds, and the other Exchange Act Class members suffered damages in connection with their purchases of Chembio common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs, on behalf of themselves and the other members of the Classes, pray for relief and judgment as follows:

A. Determining that this action is a proper class action, certifying Lead Plaintiffs as Class Representatives under Rule 23 of the Federal Rules of Civil Procedure, and appointing Co-Lead Counsel as Class counsel;

B. Awarding compensatory damages in favor of Lead Plaintiffs and the other members of the Classes against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiffs and the Classes their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages as to Count II; and

E. Awarding Lead Plaintiffs and other members of the Classes such other and further relief as the Court may deem just and proper.

JURY DEMAND

Lead Plaintiffs hereby demand a trial by jury.

DATED: February 12, 2021

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
DAVID A. ROSENFELD
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Co-Lead Counsel for Lead Plaintiffs and the Putative Classes

CERTIFICATE OF SERVICE

I, David A. Rosenfeld, hereby certify that on February 12, 2021, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ David A. Rosenfeld
DAVID A. ROSENFELD